

FDA CDRH DMC

MAR 17 2015

K150685

Received

Sky Wise Medical Instrument (Shenzhen) Co., Ltd.

(b)(4)

Cover Letter

Product: Skynector CPAP Mask

Version (b)

K140798

Cover Letter for 510(k) Additional Information

Dear FDA reviewer:

The 510(k) submission, K140798, was withdrawn due to lack of ISO10993-3 (OECD 474) test report. These days, the tests have been completed, the test reports were printed and sent to you.

The eCopy of the test reports had been sent along with the hard copy, I state herein:

eCopy Statement

Per the instructions accessed at <http://www.fda.gov/cdrh/electsub.html>, an electronic copy is being provided with these test reports and it is an exact duplicate of the original test reports.

Prior submissions statement

The prior submission for the subject device was withdrawn due to lack of ISO10993-3 (b)(4) test report. The prior submission number is (b)(4)

Please let me know if you have any questions or concerns, please feel free to contact me with E-mail or Fax. Thanks!

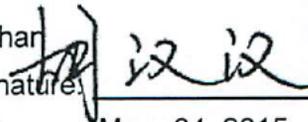
The official Correspondent information is as follow:

Name: Mr. Field.Fu

E-Mail: cefda13485@163.com

Sincerely Yours,

Management Representative: Hu hanhan

Signature: 

Date: Mar., 04, 2015

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107

Sky Wise Medical Instrument (Shenzhen) Co., Ltd.

(b)(4)

Cover L (b)(4)

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Version:A/3

K140798

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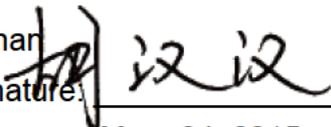
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Date: Mar., 04, 2015

Form Approved OMB No. 0910-0511 Expiration Date April 30, 2016. See Instructions for OMB Statement.

<p>DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET</p>	<p>PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.</p>																				
<p>A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover sheet.html</p>																					
<p>1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)</p> <p>SKY WISE MEDICAL INSTRUMENT CO LTD No 12 South Ping Xi Road Xinsheng Community, Longgang Street, Longgang District, Shenzhen, Guangdong, China</p> <p>CN</p> <p>1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)</p>	<p>2. CONTACT NAME Hu hanhan</p> <p>2.1 E-MAIL ADDRESS 942526346@qq.com</p> <p>2.2 TELEPHONE NUMBER (include Area code) 755-28491103</p> <p>2.3 FACSIMILE (FAX) NUMBER (Include Area code)</p>																				
<p>3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm)</p> <p>Select an application type:</p> <table border="0"> <tr> <td><input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party</td> <td>3.1 Select a center</td> </tr> <tr> <td><input type="checkbox"/> 513(g) Request for Information</td> <td><input checked="" type="checkbox"/> CDRH</td> </tr> <tr> <td><input type="checkbox"/> Biologics License Application (BLA)</td> <td><input type="checkbox"/> CBER</td> </tr> <tr> <td><input type="checkbox"/> Premarket Approval Application (PMA)</td> <td>3.2 Select one of the types below</td> </tr> <tr> <td><input type="checkbox"/> Modular PMA</td> <td><input checked="" type="checkbox"/> Original Application</td> </tr> <tr> <td><input type="checkbox"/> Product Development Protocol (PDP)</td> <td>Supplement Types:</td> </tr> <tr> <td><input type="checkbox"/> Premarket Report (PMR)</td> <td><input type="checkbox"/> Efficacy (BLA)</td> </tr> <tr> <td><input type="checkbox"/> 30-Day Notice</td> <td><input type="checkbox"/> Panel Track (PMA, PMR, PDP)</td> </tr> <tr> <td></td> <td><input type="checkbox"/> Real-Time (PMA, PMR, PDP)</td> </tr> <tr> <td></td> <td><input type="checkbox"/> 180-day (PMA, PMR, PDP)</td> </tr> </table>		<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party	3.1 Select a center	<input type="checkbox"/> 513(g) Request for Information	<input checked="" type="checkbox"/> CDRH	<input type="checkbox"/> Biologics License Application (BLA)	<input type="checkbox"/> CBER	<input type="checkbox"/> Premarket Approval Application (PMA)	3.2 Select one of the types below	<input type="checkbox"/> Modular PMA	<input checked="" type="checkbox"/> Original Application	<input type="checkbox"/> Product Development Protocol (PDP)	Supplement Types:	<input type="checkbox"/> Premarket Report (PMR)	<input type="checkbox"/> Efficacy (BLA)	<input type="checkbox"/> 30-Day Notice	<input type="checkbox"/> Panel Track (PMA, PMR, PDP)		<input type="checkbox"/> Real-Time (PMA, PMR, PDP)		<input type="checkbox"/> 180-day (PMA, PMR, PDP)
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<p>4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)</p> <p><input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA</p> <p><input checked="" type="checkbox"/> NO, I am not a small business</p> <p>4.1 If Yes, please enter your Small Business Decision Number:</p>																					
<p>5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?</p> <p><input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)</p> <p><input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)</p>																					
<p>6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.</p> <table border="0"> <tr> <td><input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates</td> <td><input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population</td> </tr> <tr> <td><input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only</td> <td><input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially</td> </tr> </table>		<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population	<input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially																
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

YES NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4)

03-Mar-2015

Form FDA 3601 (05/13)

["Close Window"](#) [Print Cover sheet](#)

K150685/801

FDA CDRH DMC

APR 13 2015

Sky Wise Medical Instrument (Shenzhen) Co., Ltd.

(b)(4)

10K Cover Letter

Product: Skynector CPAP Mask

Version: (b)(4)

SECTION 03 510 (k) Cover Letter

Basic information

Administrative Information and Basis for the Submission

Submission Date	Apr., 04,2015
Manufacturer information	Submitter's Name: Sky Wise Medical Instrument (Shenzhen) Co., Ltd. Address: No 12 South Ping Xi Road Xinsheng Community, Longgang Street, Longgang District, Shenzhen, Guangdnog, China Contact person: Hu hanhan TEL: +86-755-28491103 FAX: +86-755-28494339 E-Mail: 942526346@qq.com
Submission Correspondent	Shenzhen Joyantech Consulting Co., Ltd. 4th Floor, Jinhui Building, Nanhai BLVD, Nanshan District, Shenzhen, Guangdong, China. Contact person: Mr. Field.Fu E-Mail: cefda13485@163.com
Establishment registration number	No.
Common name of the device	nasal mask, full face mask
Trade name of the device	Skynector CPAP Mask
Type/Model of the device	FM-02, NM-03
Classification information	<u>Classification panel:</u> Anesthesiology <u>Classification name:</u> Ventilator, Non-Continuous (Respirator). <u>Regulation Number:</u> 868.5905 <u>Device Class:</u> II <u>Product Code:</u> BZD
type of 510(k) submission	Traditional
Propose of 510(k) Submission	<input checked="" type="checkbox"/> new device

Sky Wise Medical Instrument (Shenzhen) Co., Ltd.

(b)(4)

510K Cover Letter

Product: Skynector CPAP Mask

Version: (b)(4)

Predicate device	<input type="checkbox"/> modification of a legally marketed device that would not otherwise qualify for a Special 510(k) <input type="checkbox"/> new indication for use <input type="checkbox"/> new device design <input type="checkbox"/> a submission for a reprocessed, single use, disposable device <input type="checkbox"/> an exempt device which exceeds the limitations for exemption.
	510(k) number: K113127, K092835
facility information of contract sterilizers and packagers	Trade name: Mirage Quattro Full Face Mask; ComfortGel Nasal Mask.
	Product code: BZD
	registration number: not applicable
	facility name and address: not applicable
	facility address: not applicable
Compliance with standards	ISO 5356-1, ISO 10993-3, ISO 10993-5, ISO 10993-6,ISO 10993-10, ISO 17510-2,ASTM D3045.

The statement pertaining to the submission

Comparison Statement	The proposed device is substantially equivalent to the predicate devices.
eCopy Statement	Per the instructions accessed at http://www.fda.gov/cdrh/elecsb.html , an electronic copy is being provided with this submission and it is an exact duplicate of the original paper submission.
Prior submissions statement	The prior submission for the subject device was withdrawn due to lack of ISO 10993-3 (b)(4) test report. The prior submission number is (b)(4)

Express our thanks to FDA reviewer

Sky Wise Medical Instrument (Shenzhen) Co., Ltd.

(b)(4)

510K Cover Letter

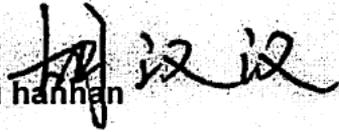
Product: Skynector CPAP Mask

Version: (b)(4)

Thank you in advance for your review of our 510(k) application and please contact the **Submission Correspondent** if anything else be required or needed.

Sincerely !

Signature: Hu hanhan



Title of signer: Management Representative

Form Approved OMB No. 0910-0511 Expiration Date April 30, 2016. See Instructions for OMB Statement.

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(b)(4)

03-Mar-2015

Form FDA 3601 (05/13)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		Form Approval OMB No. 0910-0120 Expiration Date: December 31, 2013 See PRA Statement on page 5.		
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET				
Date of Submission 04/04/2015	User Fee Payment ID Number	FDA Submission Document Number (if known) K150685		
SECTION A TYPE OF SUBMISSION				
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input checked="" type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Request for Feedback <input type="checkbox"/> Pre-Submission <input type="checkbox"/> Informational Meeting <input type="checkbox"/> Submission Issue Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Study Risk Determination <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):
Have you used or cited Standards in your submission? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (If Yes, please complete Section I, Page 5)				
SECTION B SUBMITTER, APPLICANT OR SPONSOR				
Company / Institution Name Sky Wise Medical Instrument (Shenzhen) Co., Ltd.		Establishment Registration Number (if known)		
Division Name (if applicable)		Phone Number (including area code) +86-755-28491103		
Street Address No. 12 South PingXi Road, Xinsheng Community, Longgang Street Longgang Di		FAX Number (including area code) +86-755-28494339		
City Shenzhen	State / Province guangdong	ZIP/Postal Code 518000	Country China	
Contact Name Hu Hanhan				
Contact Title Management Representative		Contact E-mail Address 942526346@qq.com		
SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)				
Company / Institution Name Shenzhen Joyantech Consulting Co., Ltd.				
Division Name (if applicable)		Phone Number (including area code) +86-0755-86069197		
Street Address 4th Floor, Jinhui Building, Nanhai BLVD, Nanshan District, Shenzhen		FAX Number (including area code) +86-0755-86069197		
City Shezhen	State / Province Guangdong	ZIP Code 518000	Country China	
Contact Name Field.Fu				
Contact Title Consultant		Contact E-mail Address cefda13485@163.com		

SECTION D1			REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager			
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment			
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address			
<input type="checkbox"/> Other Reason (<i>specify</i>):					

SECTION D2			REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing			
	<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final				
<input type="checkbox"/> Other Reason (<i>specify</i>):					

SECTION D3			REASON FOR SUBMISSION - 510(k)		
<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology			
<input checked="" type="checkbox"/> Other Reason (<i>specify</i>): The previous submission was withdrawn due to lack of ISO10993-3 (OECD 474) test report, Re-submission containing Additional Information (Deficiency) found previously was done. The previous submission Number is K140798.					

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information	
1	BZD	2		3	
5		6		7	
				<input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement	

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K113127	Mirage Quattro Full Face Mask	ResMed Limited
2	K092835	ComfortGel Nasal Mask	Respironics, Incorporated
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name
nasal mask, full face mask

	Trade or Proprietary or Model Name for This Device	Model Number
1	Skynector CPAP Mask	FM-02, NM-03
2		
3		
4		
5		

FDA document numbers of all prior related submissions (regardless of outcome)					
1	K140798	2	3	4	5
7		8	9	10	11
					12

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code BZD	C.F.R. Section (if applicable) 868 5905	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Anesthesiology		

Indications (from labeling)
 The Skynector CPAP Mask channels airflow non-invasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system.
 The Skynector CPAP Mask is to be used by adult patients (>66lb / >30kg) for whom positive airway pressure has been prescribed.
 The Skynector CPAP Mask is intended for single patient re-use in the home environment and/or multi-patient reuse in the hospital /institutional environment.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number <i>(if known)</i>
---	---------------------------------------

SECTION H	MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION
------------------	---

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name Sky Wise Medical Instrument (Shenzhen) Co., Ltd.		Establishment Registration Number	
Division Name <i>(if applicable)</i>		Phone Number <i>(including area code)</i> +86-755-28491103	
Street Address No. 12 South PingXi Road, Xinsheng Community, Longgang Street Longgang D		FAX Number <i>(including area code)</i> +86-755-28494339	
City Shenzhen	State / Province Guangdong	ZIP Code 518000	Country China
Contact Name Hu hanhan	Contact Title Management Representative	Contact E-mail Address 942526346@qq.com	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name <i>(if applicable)</i>		Phone Number <i>(including area code)</i>	
Street Address		FAX Number <i>(including area code)</i>	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name <i>(if applicable)</i>		Phone Number <i>(including area code)</i>	
Street Address		FAX Number <i>(including area code)</i>	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I UTILIZATION OF STANDARDS					
Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.					
1	Standards No. ISO 5356-1:2004	Standards Organization ISO	Standards Title Anaesthetic and respiratory equipment -- Conical connectors -- Part 1: Cones and sockets	Version Edition 3.0	Date 05/15/2004
2	Standards No. ISO 10993-5:2009	Standards Organization ISO	Standards Title Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity. (Biocompatibility)	Version Edition 3.0	Date 05/05/2010
3	Standards No. ISO 10993-10:2010	Standards Organization ISO	Standards Title Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. (Biocompatibility)	Version Edition 3.0	Date 03/16/2012
4	Standards No. ISO 10993-6:2007	Standards Organization ISO	Standards Title Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation	Version Edition 2.0	Date 04/14/2007
5	Standards No. ISO 10993-3:2003	Standards Organization ISO	Standards Title Biological evaluation of medical devices -- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	Version Edition 2.0	Date 10/15/2003
6	Standards No. ISO 17510-2:2007	Standards Organization ISO	Standards Title Sleep apnoea breathing therapy - Part 2: Masks and application accessories	Version Edition 2.0	Date 10/01/2007
7	Standards No. ASTM D3045-92	Standards Organization ASTM	Standards Title Standard Practice for Heat Aging of Plastics Without Load	Version Edition 1.0	Date 11/15/1992
Please include any additional standards to be cited on a separate page.					
<p>This section applies only to requirements of the Paperwork Reduction Act of 1995.</p> <p>*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.*</p> <p>The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:</p> <p style="text-align: center;">Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff 1350 Piccard Drive, Room 400 Rockville, MD 20850</p> <p style="text-align: center;"><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i></p>					

Sky Wise Medical Instrument (Shenzhen) Co., Ltd. (b)(4) 510K Cover Letter
 Product: Skynector CPAP Mask Version (b)(4)

SECTION 03 510 (k) Cover Letter

Basic information

Administrative Information and Basis for the Submission

Submission Date	Apr., 04,2015
Manufacturer information	Submitter's Name: Sky Wise Medical Instrument (Shenzhen) Co., Ltd. Address: No 12 South Ping Xi Road Xinsheng Community, Longgang Street, Longgang District, Shenzhen, Guangdnog, China
Submission Correspondent	Contact person: Hu hanhan TEL: +86-755-28491103 FAX: +86-755-28494339 E-Mail: 942526346@qq.com Shenzhen Joyantech Consulting Co., Ltd. 4th Floor, Jinhui Building, Nanhai BLVD, Nanshan District, Shenzhen, Guangdong, China. Contact person: Mr. Field.Fu E-Mail: cefda13485@163.com
Establishment registration number	No.
Common name of the device	nasal mask, full face mask
Trade name of the device	Skynector CPAP Mask
Type/Model of the device	FM-02, NM-03
Classification information	<u>Classification panel:</u> Anesthesiology <u>Classification name:</u> Ventilator, Non-Continuous (Respirator). <u>Regulation Number:</u> 868.5905 <u>Device Class:</u> II <u>Product Code:</u> BZD
type of 510(k) submission	Traditional
Propose of 510(k) Submission	<input checked="" type="checkbox"/> new device

Sky Wise Medical Instrument (Shenzhen) Co., Ltd. (b)(4) 510K Cover Letter
 Product: Skynektor CPAP Mask Version (b)(4)

Predicate device	<input type="checkbox"/> modification of a legally marketed device that would not otherwise qualify for a Special 510(k) <input type="checkbox"/> new indication for use <input type="checkbox"/> new device design <input type="checkbox"/> a submission for a reprocessed, single use, disposable device <input type="checkbox"/> an exempt device which exceeds the limitations for exemption.
	510(k) number: K113127, K092835 Trade name: Mirage Quattro Full Face Mask; ComfortGel Nasal Mask. Product code: BZD
facility information of contract sterilizers and packagers	registration number: not applicable facility name and address: not applicable facility address: not applicable
Compliance with standards	ISO 5356-1, ISO 10993-3, ISO 10993-5, ISO 10993-6,ISO 10993-10, ISO 17510-2,ASTM D3045.

The statement pertaining to the submission

Comparison Statement	The proposed device is substantially equivalent to the predicate devices.
eCopy Statement	Per the instructions accessed at http://www.fda.gov/cdrh/elecsup.html , an electronic copy is being provided with this submission and it is an exact duplicate of the original paper submission.
Prior submissions statement	The prior submission for the subject device was withdrawn due to lack of ISO 10993-3 (b)(4) test report. The prior submission number is (b)(4).

Express our thanks to FDA reviewer

Sky Wise Medical Instrument (Shenzhen) Co., Ltd.

(b)(4)

510K Cover Letter

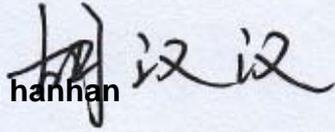
Product: Skynector CPAP Mask

Version: (b)

Thank you in advance for your review of our 510(k) application and please contact the **Submission Correspondent** if anything else be required or needed.

Sincerely !

Signature: Hu hanhan



Title of signer: Management Representative

Sky Wise Medical Instrument (Shenzhen) Co., Ltd.

(b)(4) 510K Cover Letter

Product: Skynector CPAP Mask

Version: (b)

3.2 Design and Use of the Device

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does the device contain components derived from a tissue or other biologic source?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is the device provided sterile?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is the device intended for single use?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is the device a reprocessed single use device?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, does this device type require reprocessed validation data?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does the device contain a drug?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does the device contain a biologic?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does the device use software?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does the submission include clinical information?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is the device implanted?	<input type="checkbox"/>	<input checked="" type="checkbox"/>

3.3 Screening Checklist

The following table is based on "Guidance for Industry and FDA Staff - Format for Traditional and Abbreviated 510(k)s".

Item	Title	Related Information	Adequate Yes/No/NA	Location
1	MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet www.fda.gov/oc/mdufma/cover sheet.html	Yes	SEC 01
2	CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Cover Sheet www.fda.gov/opacom/morechoices/fdaforms/FDA-3514.pdf	Yes	SEC 02
3	510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	Yes	SEC 03
4	Indications for Use Statement	Device Advice "Content of a 510(k)" Section D www.fda.gov/cdrh/devadvice/314312.html#link_6	Yes	SEC 04
5	510(k) Summary or 510(k) Statement	Device Advice "Content of a 510(k)" Section E www.fda.gov/cdrh/devadvice/314312.html#link_7	Yes	SEC 05
6	Truthful and Accuracy Statement	Device Advice "Content of a 510(k)" Section G www.fda.gov/cdrh/devadvice/314312.html#link_9	Yes	SEC 06

Sky Wise Medical Instrument (Shenzhen) Co., Ltd.

(b)(4)

510K Cover Letter

Product: Skyneotor CPAP Mask

Version: (b)

Item	Title	Related Information	Adequate Yes/No/NA	Location
7	Class III Summary and Certification	Class III Summary and Certification Form www.fda.gov/cdrh/manual/stmnciii.html	NA	SEC 07
8	Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf Financial Disclosure by Clinical Investigators www.fda.gov/oc/guidance/financialdis.html .	NA	SEC 08
9	Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	Use of Standards in Substantial Equivalence Determinations www.fda.gov/cdrh/ode/guidance/1131.html . FDA Standards program www.fda.gov/cdrh/stdsprog.html . Declaration of conformity www.fda.gov/cdrh/devadvice/3145.html#link_9 Required Elements for Declaration of Conformity to Recognized Standard www.fda.gov/cdrh/ode/regrecstand.html	NA	SEC 09
10	Executive Summary	See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	Yes	SEC 10
11	Device Description	See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	Yes	SEC 11
12	Substantial Equivalence Discussion	Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3), www.fda.gov/cdrh/k863.html	Yes	SEC 12
13	Proposed Labeling	Device Advice "Content of a 510(k)" Section H www.fda.gov/cdrh/devadvice/314312.html#link_10	Yes	SEC 13
14	Sterilization/Disinfection/Cleaning/ Shelf Life	Updated 510(k) Sterility Review Guidance (K90-1) www.fda.gov/cdrh/ode/guidance/361.html For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket	Cleaning/ Disinfection is applicable, the other is not.	SEC 14

Sky Wise Medical Instrument (Shenzhen) Co., Ltd.

(b)(4)

510K Cover Letter

Product: Skynektor CPAP Mask

Version: (b)

Item	Title	Related Information	Adequate Yes/No/NA	Location
		Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices www.fda.gov/cdrh/ode/guidance/1216.html		
15	Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" www.fda.gov/cdrh/g951.html	Yes	SEC 15
16	Software	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices www.fda.gov/cdrh/ode/software.html	NA	SEC 16
17	Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program www.fda.gov/cdrh/emc See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)	NA	SEC 17
18	Performance Testing – Bench	See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	Yes	SEC 18
19	Performance Testing – Animal	See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	NA	SEC 19
20	Performance Testing – Clinical	http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048364.pdf	NA	SEC 20
21	Standards Data Report Form - Form 3654	FORM FDA 3654, Standards Data Report for 510(k)s	Yes	SEC 21
22	Other	Risk management report	Yes	SEC 22

Sky Wise Medical Instrument (Shenzhen) Co., Ltd.

(b)(4)

10K Cover Letter

Product: Skynektor CPAP Mask

Version: (b)

b

3.4 Table of Contents

- SEC 01: Vol_001_MDUF Cover Sheet
 - 001_MDUF Cover Sheet
- SEC 02: Vol_002_CDRH Premarket Review Submission Cover Sheet
 - 001_CDRH Premarket Review Submission Cover Sheet
- SEC 03: Vol_003_Cover Letter
 - 001_Cover Letter
- SEC 04: Vol_004_Indications for Use Statement
 - 001_Indications for Use
- SEC 05: Vol_005_510k Summary
 - 001_510k Summary
- SEC 06: Vol_006_Truth and Accurate Statement
 - 001_Truth and Accurate Statement
- SEC 07: Vol_007_Class III Summary and Certification (**not applicable**)
 - 001_Class III Summary and Certification (**not applicable**)
- SEC 08: Vol_008_Financial Certification (**not applicable**)
 - 001_Financial Certification (**not applicable**)
- SEC 09: Vol_009_Declarations of Conformity and Summary Reports
 - (Abbreviated 510(k)s) (**not applicable**)
 - 001_Declarations of Conformity and Summary Reports
 - (Abbreviated 510(k)s) (**not applicable**)
- SEC 10 : Vol_010_Executive Summary
 - 001_Executive Summary
- SEC 11: Vol_011_Device Description
 - 001_Device Description
- SEC 12: Vol_012_Substantial Equivalence Comparison
 - 001_Substantial Equivalence Discussion;
 - 002_K113127;
 - 003_K092835.
- SEC 13: Vol_013_Proposed Labeling
 - 001_FM-02 label;
 - 002_NM-03 label;
 - 003_FM-02 User Guide;

Sky Wise Medical Instrument (Shenzhen) Co., Ltd. (b)(4) _510K Cover Letter
Product: Skynector CPAP Mask Version (b)
b

- 004_NM-03 User Guide.
- SEC 14: Vol_014_Cleaning Validation and shelf life
 - 001_Cleaning disinfection and Shelf Life;
 - 002_Mask Cleaning and Disinfection test report.
- SEC 15: Vol_015_Biocompatibility
 - 001_Contents of Biocompatibility;
 - 002_(b)(4) Annex 1;
 - 003_(b)(4) Annex 2;
 - 004_(b)(4) Annex 3;
 - 005_(b)(4) Annex 4;
 - 006_(b)(4) Annex 5.
- SEC 16: Vol_016_Software (**not applicable**)
 - 001_Software (**not applicable**)
- SEC 17: Vol_017_Electrical Safety and Electromagnetic Compatibility (**not applicable**)
 - 001_Electromagnetic Compatibility and Electrical Safety (**not applicable**)
- SEC 18: Vol_018_Performance Testing – Bench
 - 001_Connecting Test Report for the Connector Used on FM-05 Apnea Mask;
 - 002_Leak rate test report;
 - 003_Resistance to flow (Pressure drop) test report;
 - 004_Anti-asphyxia valve pressure test report;
 - 005_Breathing during single fault condition-Determination of the inspiratory and expiratory resistance;
 - 006_CO2 rebreathing test report;
 - 007_Vibration and noise test report;
 - 008_Dead space test report.
- SEC 19: Vol_019_Performance Testing – Animal (**not applicable**)
 - 001_Performance Testing – Animal (**not applicable**)
- SEC 20: Vol_020_performance test: Clinical (**not applicable**)
 - 001_Clinical testing (**not applicable**)
 - 002_Certification of Compliance with Clinical Form FDA 3674
- SEC 21: Vol_021_Standards Data Report

Sky Wise Medical Instrument (Shenzhen) Co., Ltd. (b)(4) _510K Cover Letter
Product: Skynector CPAP Mask Version: (b)(4)

- 001_Standard Data Report for ISO 5356-1
- 002_Standard Data Report for ISO 10993-5
- 003_Standard Data Report for ISO 10993-10
- 004_Standard Data Report for ISO 10993-6
- 005_Standard Data Report for ISO 10993-3
- 006_Standard Data Report for ISO 17510-2
- 007_Standard Data Report for ASTM D3045

SEC 22: Vol_022_Risk management report

- 001_Risk management report

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: December 31, 2013

See PRA Statement on last page.

Indications for Use

510(k) Number (if known)

Device Name

Skynector CPAP Mask

Indications for Use (Describe)

The Skynector CPAP Mask channels airflow non-invasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system.

The Skynector CPAP Mask is to be used by adult patients (>66lb / >30kg) for whom positive airway pressure has been prescribed.

The Skynector CPAP Mask is intended for single patient re-use in the home environment and/or multi-patient reuse in the hospital / institutional environment.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Food and Drug Administration
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PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Sky Wise Medical Instrument (Shenzhen) Co., Ltd.

(b)(4) _510K Summary

Product: Skynector CPAP Mask

Version (b)
b)

SECTION 05 510(k) Summary

This summary of 510(K) safety and effectiveness information is submitted as Required by requirements of SMDA and 21 CFR §807.92.

1 Administrative Information

Date of Summary prepared
Manufacturer information

Apr, 04, 2015

Company title:
Sky Wise Medical Instrument (Shenzhen) Co., Ltd.

Company address:

No 12 South Ping Xi Road Xinsheng
Community, Longgang Street, Longgang
District, Shenzhen, Guangdong, China

Phone: +86-755-28491103

Fax: +86-755-28494339

Contact Person: Hu hanhan

E-mail: 942526346@qq.com

Submission Correspondent

Shenzhen Joyantech Consulting Co., Ltd.
4th Floor, Jinhui Building, Nanhai BLVD,
Nanshan District, Shenzhen, Guangdong,
China.

Contact person: Mr. Field.Fu

E-Mail: cefda13485@163.com

QQ: 670312758

Website: www.cefda.com

No.



卓远天成

Establishment registration number

2 Device Information

Type of 510(k) submission:

Traditional

Trade Name:

Skynector CPAP Mask

Model:

FM-02, NM-03

Sky Wise Medical Instrument (Shenzhen) Co., Ltd.

(b)(4)

_510K Summary

Product: Skynector CPAP Mask

Version (b)

Classification name:	Ventilator, Non-Continuous (Respirator).
Review Panel:	Anesthesiology
Product Code:	BZD
Device Class:	II
Regulation Number:	868.5905

3 Predicate Device Information

Sponsor:	ResMed Limited; Respironics, Incorporated.
Device:	Mirage Quattro Full Face Mask; ComfortGel Nasal Mask.
510(K) Number:	K113127, K092835

4 Device Description

The Skynector CPAP masks are designed based on human facial shape and structure, and the operating characteristics during application, they are injection mold of hard PC plastic and soft silicone rubber materials, with the characteristics of good gas tightness, convenient operation and comfortable to wear, etc. They are used for the interfacing devices that are used for provide users with Continuous Positive Airway Pressure (CPAP) ventilation or biphasic positive airway pressure (BiPAP) ventilation treatment.

5 Intended Use

The Skynector CPAP Mask channels airflow non-invasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system.

The Skynector CPAP Mask is to be used by adult patients (>66lb / >30kg) for whom positive airway pressure has been prescribed.

The Skynector CPAP Mask is intended for single patient re-use in the home environment and/or multi-patient reuse in the hospital /institutional environment.

6 Indications for Use

The Skynector CPAP Mask channels airflow non-invasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system.

The Skynector CPAP Mask is to be used by adult patients (>66lb / >30kg) for whom positive airway pressure has been prescribed.

The Skynector CPAP Mask is intended for single patient re-use in the home environment and/or multi-patient reuse in the hospital /institutional environment.

7 Technological characteristics of the proposed device compared to the predicate device

The proposed device and the Predicate device have the same intended use, design principle, and similar material composition. The differences do not exert adverse effect on the proposed device. The proposed device is substantially equivalent to the predicate devices.

8 Brief discussions of the nonclinical tests

Skynector CPAP Masks conform to the following standards:

- ✧ ISO 5356-1:2004 Anaesthetic and respiratory equipment -- Conical connectors -- Part 1: Cones and sockets;
- ✧ ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for In Vitro cytotoxicity;
- ✧ ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization;
- ✧ ISO 10993-6:2007 Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation;
- ✧ ISO 10993-3:2003 Biological evaluation of medical devices -- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity;
- ✧ ISO 17510-2:2007 Sleep apnoea breathing therapy - Part 2: Masks and application accessories;
- ✧ ASTM D3045-92 Standard Practice for Heat Aging of Plastics Without Load.

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(b)(4) _510K Summary

Product: Skynector CPAP Mask

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The performance test based on ISO 17510-2:2007 are as follow:

No.	The title of test report	Items or Annex in ISO 17510-2:2007
01	001_Connecting Test Report for the Connector Used on FM-05 Apnea Mask	Item 5.1
02	002_Leak rate test report	Annex B
03	003_Resistance to flow (Pressure drop) test report	Annex C
04	004_Anti-asphyxia valve pressure test report	Annex D
05	005_Breathing during single fault condition-Determination of the inspiratory and expiratory resistance	Annex E
06	006_CO2 re-breathing test report	Annex F
07	007_Vibration and noise test report	Annex G
08	008_Dead space test report	Not requested by standard, but conducted on predicate device

9 Brief discussions of clinical tests

Not applicable.

10 Other information (such as required by FDA guidance)

No other information.

11 Conclusions

The subject device--- Skynector CPAP Mask (FM-02, NM-03) are respectively substantially equivalent to Mirage Quattro Full Face Mask(K113127), ComfortGel Nasal Mask(K092835).

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Truthful and Accurate Statement

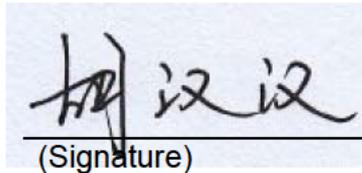
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SECTION 06 Truthful and Accurate Statement

(As Required By 21 CFR 807.87(k))

I certify that, in my capacity as **Management Representative of Sky Wise Medical Instrument (Shenzhen) Co., Ltd.**, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



(Signature)

Hu Hanhan

(Typed Name)

Apr., 04, 2015

(Date)

Sky Wise Medical Instrument (Shenzhen) Co., Ltd. (b)(4) _Class III Summary and Cert.
Product: Skynector CPAP Mask Version: (b)

SECTION 07 Class III Summary and Certification

(not applicable)

(As Required by 21 CFR 807.94)

(To be submitted when claiming equivalence to a Class III device)

This section is not applicable, for the device is class II, not III.

Sky Wise Medical Instrument (Shenzhen) Co., Ltd.	(b)(4)	Financial Certification
Product: Skynector CPAP Mask		Version (b)

SECTION 08 Financial Certification (not applicable)

This section is not applicable, for clinical test does not apply to the proposed device.

Sky Wise Medical Instrument (Shenzhen) Co., Ltd. (b)(4) Declarations of Conformity or Summary Reports
Product: Skynector CPAP Mask Version: (b)

**SECTION 09 Declarations of Conformity and Summary Reports
(not applicable)**

This section is not applicable, for this 510K is traditional one, not abbreviated.

SECTION 10 Executive Summary

1 Concise description of the device

1.1 intended use/Indications for use

The Skynector CPAP Mask channels airflow non-invasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system.

The Skynector CPAP Mask is to be used by adult patients (>661b / >30kg) for whom positive airway pressure has been prescribed.

The Skynector CPAP Mask is intended for single patient re-use in the home environment and/or multi-patient reuse in the hospital /institutional environment.

1.2 Technologies

(1) Principle

The Skynector CPAP masks are designed based on human facial shape, structure, and the operating characteristics during application. They are injection molded of hard PC plastic and soft silicone rubber materials, with the characteristics of good gas tightness, convenient operation and comfortable to wear, etc.

(2) Materials

There are 6 kinds of patient contacting materials –Silicone Rubber, Polypropylene, Polycarbonate, Polyvinylchloride, nylon and polyester. The 6 kinds of materials (or their combination) respectively constitute the different components.

All the patient contacting materials had been conducted biocompatibility test, the test report is in VOL 15.

(3) Cleaning, Disinfection and Sterilization

There is no sterilization in this 510(k) submission.

Cleaning/disinfecting instructions are described in the user manual (refer to VOL 13 of this submission). The cleaning/disinfecting method and detergent are similar with the predicate device, the cleaning/disinfecting validation report is provided in this submission, refer to VOL 14.

(4) Software

The device does not contain any software and firmware.

(5) Labeling

We provide the labeling for the subject device in VOL 13 of the 510(k) submission, including the following elements:

- ◇ device label;
- ◇ user manual.

2 Device Comparison table

The performance and safety of Urinary Incontinence Probe primarily rest with intended use, indication for use, target population, the location where used, patient contact materials, that is to say, according to the 510(k) "Substantial Equivalence" Decision Making Process, SE determination can be deemed including the following 3 parts: Part A is comparison of indication statement; Part B is comparison of Technological characteristics(performance and safety), and Part C is discussion of Supporting data(performance and/or clinic and so on).

Comparison items between the proposed device and the predicate and concise discussion are as follow:

Comparison between the proposed device and the predicate (K113127, K092835)

Elements of Comparison	Conclusion	Remarks
Part A: Comparison of indication statement		
intended use	Substantial Equivalence	Narrative Words are different, the contents are same.
Indications for use	Substantial Equivalence	
target population	same	
anatomical sites	same	
Prescription or OTC	same	
where used (hospital, home, ambulance, etc)	same	
Part B: Comparison of Technological characteristics		

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Executive Summary

Product: Skynector CPAP Mask

Version (b)

Elements of Comparison	Conclusion	Remarks
Design/operation principle	same	
Materials	different	The materials of the Synector Apnea Mask are the same as the predicate except for the faceplate, which is made of medical-grade polycarbonate or medical-grade polypropylene, the biocompatibility of all materials were assessed based on ISO 10993, the testing results showed that the materials complied with ISO 10993, the differences in materials of the faceplate will not affect its safety and effectiveness. The materials were deemed as safe for use.
Contact duration	same	
Cleaning method	same	
Dimensions	different	The dimensions of the subject device are not fully same as the predicate, but they are within the normal range of human facial figure.
standards met	Same	
biocompatibility	Same	
Part C: Discussion of Supporting data		
As remarked in Part B, the material of faceplate is different from the predicate, The biocompatibility of all materials were assessed based on ISO 10993, the testing results showed that the materials of faceplate and other materials complied with ISO 10993; the dimensions are also different from the predicate, but they are within the normal range of human facial figure.		

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Executive Summary

Product: Skynector CPAP Mask

Version (b)

Elements of Comparison	Conclusion	Remarks
Conclusion:		
The subject devices have all features of the predicate device. The few differences do not affect the safety and effectiveness of the subject devices.		
Thus, the subject devices are substantially equivalent to the predicate device.		

The detailed comparison and discussion are described in VOL 12.

3 Concise summaries for performance testing---bench

The subject device was tested based on the following standards and the results are "PASS".

Testing performed	Standard	Standard Title	Testing institution	Conclusion	Remark
Connector performance	ISO 5356-1:2004	Anaesthetic and respiratory equipment -- Conical connectors -- Part 1: Cones and sockets	(b)(4)		
Aging	ASTM D3045-92	Standard Practice for Heat Aging of Plastics Without Load			
Mask performance*	ISO 17510-2:2007	Sleep apnoea breathing therapy - Part 2: Masks and application accessories			
Biocompatibility	ISO 10993-3:2003	Biological evaluation of medical devices -- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity			
Biocompatibility	ISO 10993-5:2009	Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity			
Biocompatibility	ISO 10993-6:2007	Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation			

Sky Wise Medical Instrument (Shenzhen) Co., Ltd.

SEC_010: 001_Executive Summary

Product: Skynector CPAP Mask

Version:A/0

Testing performed	Standard	Standard Title	Testing institution	Conclusion	Remark
Biocompatibility	ISO 10993-10: 2010	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity	(b)(4)		

* The details for Mask Performance Tests

No.	The title of test report	Items or Annex in ISO 17510-2:2007	Location in this submission
01	001_Connecting Test Report for the Connector Used on FM-05 Apnea Mask	Item 5.1	VOL-018
02	002_Leak rate test report	Annex B	VOL-018
03	003_Resistance to flow (Pressure drop) test report	Annex C	VOL-018
04	004_Anti-asphyxia valve pressure test report	Annex D	VOL-018
05	005_Breathing during single fault condition-Determination of the inspiratory and expiratory resistance	Annex E	VOL-018
06	006_CO2 rebreathing test report	Annex F	VOL-018
07	007_Vibration and noise test report	Annex G	VOL-018
08	008_Dead space test report	Not requested by standard, but conducted on predicate device	VOL-018

4 Concise summaries for performance testing---animal

The animal testing is not applicable to the subject device.

5 Concise summary for performance testing ---clinical

The clinical testing is not necessary, for the safety and effectiveness of the product did not depend on clinical test, the bench test is adequate.

6 Conclusions

Therefore, the subject devices are substantial equivalent as predicate device for safety and effectiveness.

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(b)(4) Device Description

Product: Skynector CPAP Mask

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SECTION 11 Device Descriptions

1 Narrative descriptions

1.1 General Information:

Trade Name: Skynector CPAP Mask

Models: FM-02, NM-03

Common Name: full face mask, nasal mask.

Classification Name: Ventilator, Non-Continuous (Respirator)

Regulation Description: Noncontinuous ventilator (IPPB).

Regulation Medical Specialty: Anesthesiology

Product Code: BZD

Regulation Number: 868.5905

Device Class: 2

1.2 Intended Use/ Indication For Use:

The Skynector CPAP Mask channels airflow non-invasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system.

The Skynector CPAP Mask is to be used by adult patients (>66lb / >30kg) for whom positive airway pressure has been prescribed.

The Skynector CPAP Mask is intended for single patient re-use in the home environment and/or multi-patient reuse in the hospital /institutional environment.

1.3 Contraindication in the application of the Skynector CPAP mask:

The masks should not be used if the patient is unresponsive or unable to remove the mask by themselves, and it is not recommended for patients who are taking a prescription drug that may cause vomiting.

1.4 Principles of operation:

The Skynector CPAP masks are designed based on human facial shape, structure, and the operating characteristics during application. They are injection molded of hard PC plastic and soft silicone rubber materials, with the characteristics of good gas tightness, convenient operation and comfortable to wear, etc.

1.5 Composition:

The products consist of forehead pad, cushion, valve, faceplate, bracket, swivel, connector,

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_Device Description

Product: Skynector CPAP Mask

Version: (b)

vent, elbow, pick off port, headgear and so on, and all materials contact the patient. Refer to the "Table: Patient contacting materials" for details.

1.6 The typical device with which the proposed device will be used

(In the case the proposed device is an accessory or component sold to an end-user)

The CPAP (Continuous Positive Airway Pressure) or Bi-level system

2 physical or technical descriptions

2.1 Photographs or pictures

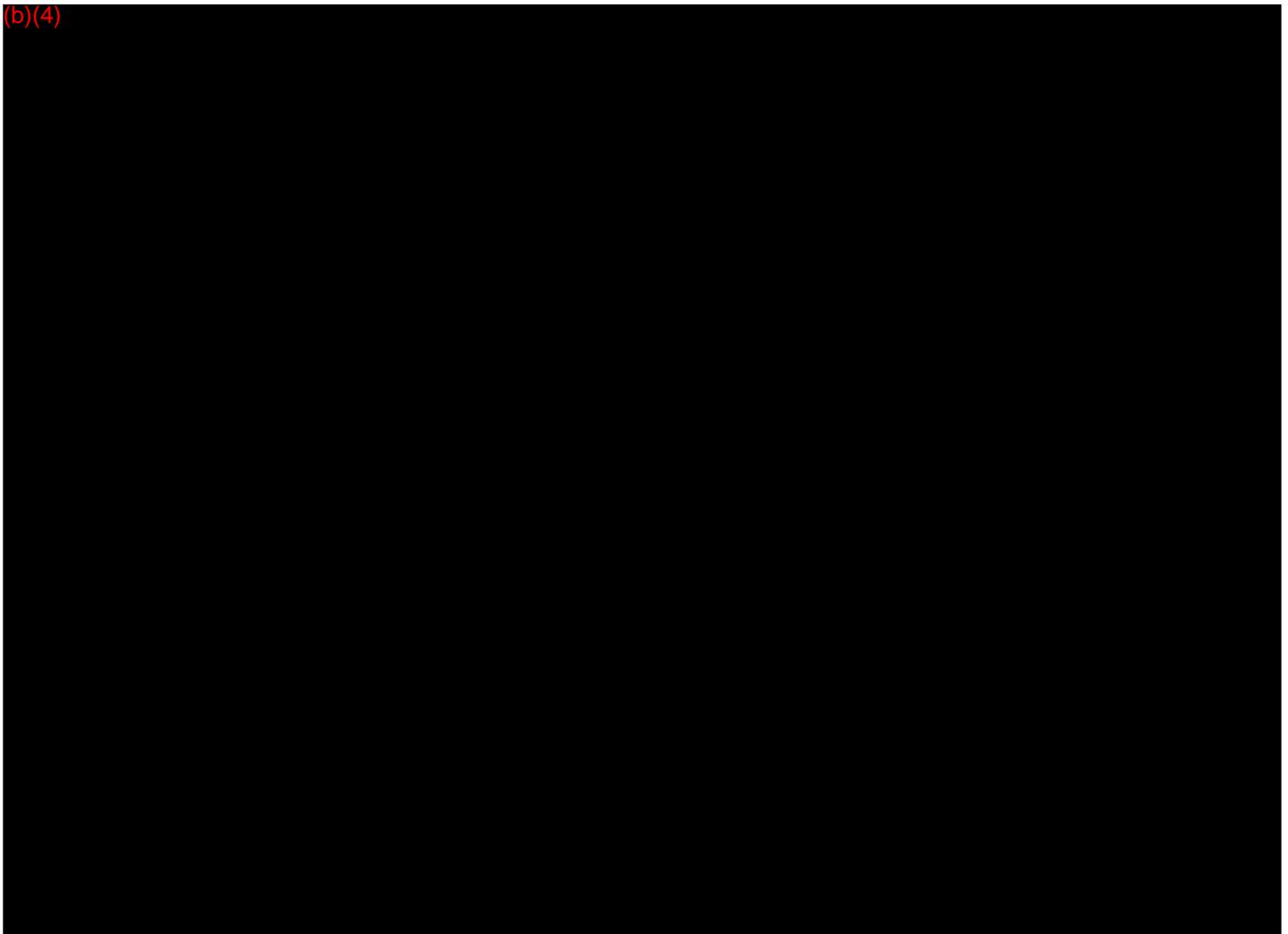


Figure 1 Schematic diagram of FM-02 full-face mask

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(b)(4) Device Description

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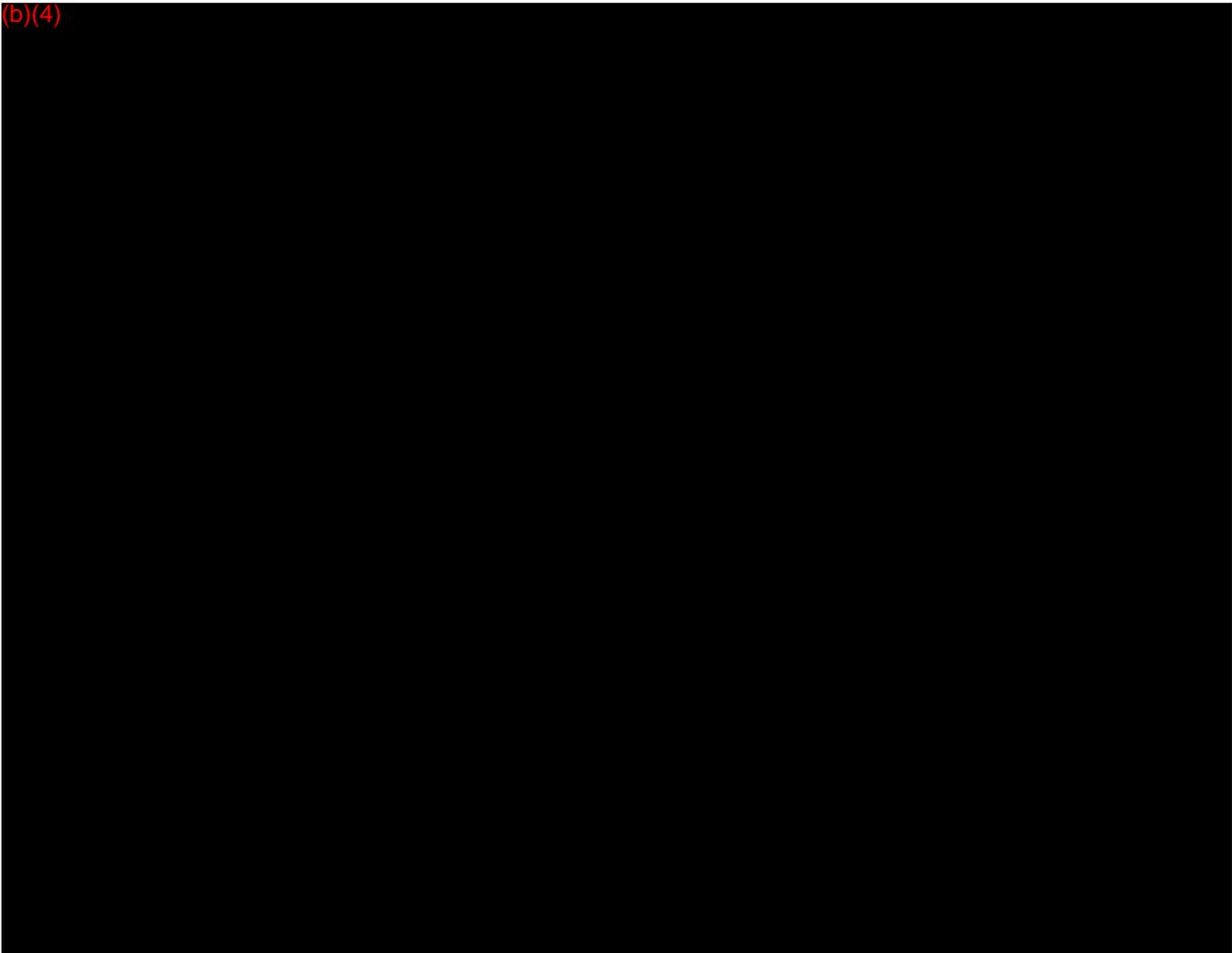


Figure 2 Schematic diagram of NM-03 nasal mask

2.2 Engineering drawings

It is unnecessary. The products can be understood alone by pictures and other sub-sections in this section.

2.3 Parts which are intended for single use

Not applicable, the proposed device doesn't contain any party which is intended for single use.

2.4 Patient contact materials

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_Device Description

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There are 6 kinds of patient contacting materials –Silicone Rubber, Polypropylene, Polycarbonate, Polyvinylchloride, nylon and polyester. The 6 kinds of materials (or their combination) respectively constitute the different components, there are not any other ingredients, including plastisizers, additives, cross linkers, reagents, colorants, inks, adhesives, surfactants, detergents, etc., used during the manufacture of the subject device models.

The biocompatibility tests were performed on the 6 kinds of patient contacting materials mentioned above, and the corresponding components are in status of finished product, either assembled into finished mask, or disassembled mechanically from the finished mask, the relevant contacting manner, duration, applicable standards and testing report No. of the tests are listed in 001_Contents of Biocompatibility in VOL_015.

Table 01: Patient contacting materials

Model	Components	Materials	Contacting manner and duration	Applicable standards
Full-face Mask FM-02	forehead pad	Silicone Rubber	Skin, permanent	ISO 10993-5, -10
	cushion	Silicone Rubber	tissue, permanent	ISO 10993-3,-6, ISO 10993-5, -10
	valve	Silicone Rubber	tissue, permanent	ISO 10993-3,-6, ISO 10993-5, -10
	faceplate	Polypropylene	Skin, limited	ISO 10993-5, -10
	bracket	Polycarbonate	Skin, limited	ISO 10993-5, -10
	swivel	Polycarbonate	tissue, permanent	ISO 10993-3,-6, ISO 10993-5, -10
	connector	Polycarbonate	tissue, permanent	ISO 10993-3,-6, ISO 10993-5, -10
	vent	Polycarbonate	tissue, permanent	ISO 10993-3,-6, ISO 10993-5, -10
	elbow	Polycarbonate	tissue, permanent	ISO 10993-3,-6, ISO 10993-5, -10
	pick off port	Polyvinylchloride	Skin, permanent	ISO 10993-5, -10
	headgear	nylon, polyester	Skin, permanent	ISO 10993-5, -10
	elbow	Polycarbonate	tissue, permanent	ISO 10993-3,-6, ISO 10993-5, -10
	pick off port	Polyvinylchloride	Skin, permanent	ISO 10993-5, -10
	headgear	nylon, polyester	Skin, permanent	ISO 10993-5, -10
	connector	Polycarbonate	tissue, permanent	ISO 10993-3,-6, ISO 10993-5, -10

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Model	Components	Materials	Contacting manner and duration	Applicable standards
	vent	Polycarbonate	tissue, permanent	ISO 10993-3,-6, ISO 10993-5, -10
	elbow	Polycarbonate	tissue, permanent	ISO 10993-3,-6, ISO 10993-5, -10
	pick off port	Polyvinylchloride	Skin, permanent	ISO 10993-5, -10
	headgear	nylon, polyester	Skin, permanent	ISO 10993-5, -10
Nasal mask NM-03	forehead pad	Silicone Rubber	Skin, permanent	ISO 10993-5, -10
	cushion	Silicone Rubber	tissue, permanent	ISO 10993-3,-6, ISO 10993-5, -10
	faceplate	Polycarbonate	Skin, limited	ISO 10993-5, -10
	bracket	Polycarbonate	Skin, limited	ISO 10993-5, -10
	support arm assembly	Polycarbonate	Skin, limited	ISO 10993-5, -10
	cushion clip	Polycarbonate	Skin, limited	ISO 10993-5, -10
	gasket	Polycarbonate	tissue, permanent	ISO 10993-3,-6, ISO 10993-5, -10
	swivel	Polycarbonate	tissue, permanent	ISO 10993-3,-6, ISO 10993-5, -10
	vent	Polycarbonate	tissue, permanent	ISO 10993-3,-6, ISO 10993-5, -10
	elbow	Polycarbonate	tissue, permanent	ISO 10993-3,-6, ISO 10993-5, -10
	pick off port	Polyvinylchloride	Skin, permanent	ISO 10993-5, -10
headgear	nylon, polyester	Skin, permanent	ISO 10993-5, -10	

2.5 Technical specification

2.5.1 Mask models and sizes

Table 02: Mask Models and sizes

Specifications and models		Specifications and models description	Size (mm)		
			L	W	H
Nasal mask	NM-03L	Large size	157	106	90
	NM-03M	Medium size	155.5	105.5	89
	NM-03S	Small size	155.5	95	90.5

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Full-face mask	FM-02L	Large size	215	120.5	130
	FM-02M	Medium size	215	115.5	130
	FM-02S	Small size	215	115.5	126

2.5.2 Pressure range the interface intended to deliver

4~20cmH₂O

2.5.3 Connection performance

a) Connector

The 22mm conical connector specified in ISO5356 should be adopted for the windpipe interface of the CPAP mask and the pipe joints used to connect with the machine.

b) Connection strength

The connections between the connector and faceplate of the CPAP mask and the connections between mask components, should be able to withstand not less than the static tensile force of 15N for15s, the components should keep tightness.

2.5.4 The anti-asphyxia valve specifications

Table 03: The Anti-asphyxia valve specifications

Specifications and models		Opening pressure(deactivation pressure) (cmH ₂ O)	Closing pressure(activation pressure) (cmH ₂ O)
Full-Face mask	FM-02L	0.5	0.8
	FM-02M	0.4	0.8
	FM-02S	0.4	0.8

2.5.5The gas volume in dead space

Table 04: The gas volume in dead space

Specifications and models		Specification and models description	Gas volume of dead space
Nasal mask	NM-03L	L	180ml

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	NM-03M	M	160ml
	NM-03S	S	150ml
Full-Face mask	FM-02L	L	358ml
	FM-02M	M	311ml
	FM-02S	S	280ml

2.5.6 The exhaust leak rate in the connections

Table 05: The exhaust leak rate of Nasal Mask

Size	vent leak rate (unit: L / min)				
	Pressure (unit:cmH2O)				
	4	10	20	30	40
NM-03L	19	27	38	46	53
NM-03M	19	28	39	48	56
NM-03S	17	26	38	48	52

Table 06: The exhaust leak rate of the Full-face Mask

Size	vent leak rate (unit: L / min)				
	Pressure (unit:cmH2O)				
	4	10	20	30	40
FM-02L	34	46	60	72	82
FM-02M	30	42	57	67	74
FM-02S	28	40	55	65	72

2.5.7 Resistance (Drop in pressure measured) of the masks

Table 07: Resistance (Drop in pressure)

Specifications and models		Flow(L/min)	Resistance (Drop in pressure) (Unit:cmH ₂ O)
Full-Face mask	FM-02L, FM-02M,	100L/min	1.5
	FM-02S	50L/min	0.5
	NM-03L, NM-03M,	100L/min	0.3

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	NM-03S	50L/min	0.1
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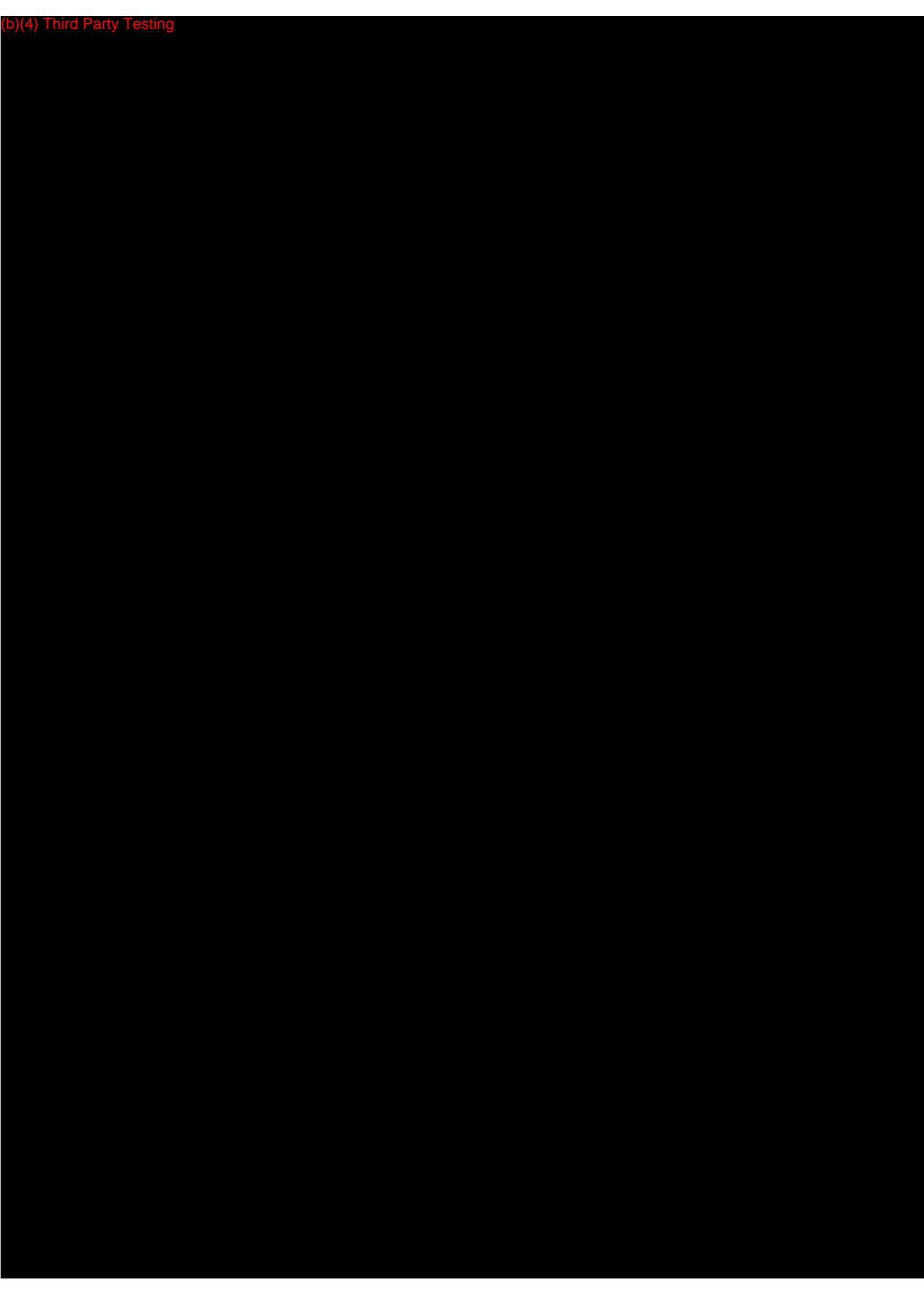
3. The transportation and preservation of the Skynector CPAP masks

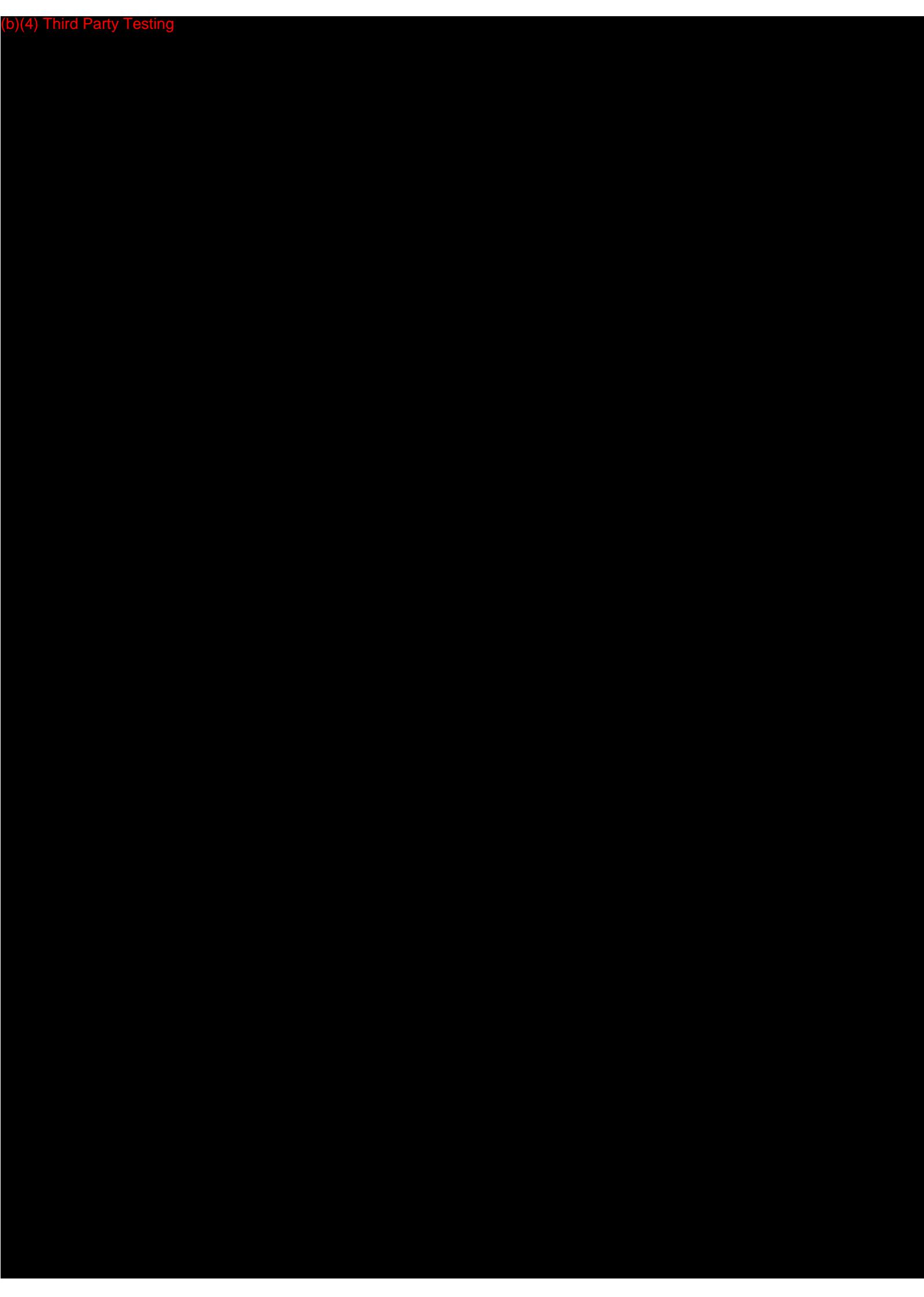
3.1 Transportation

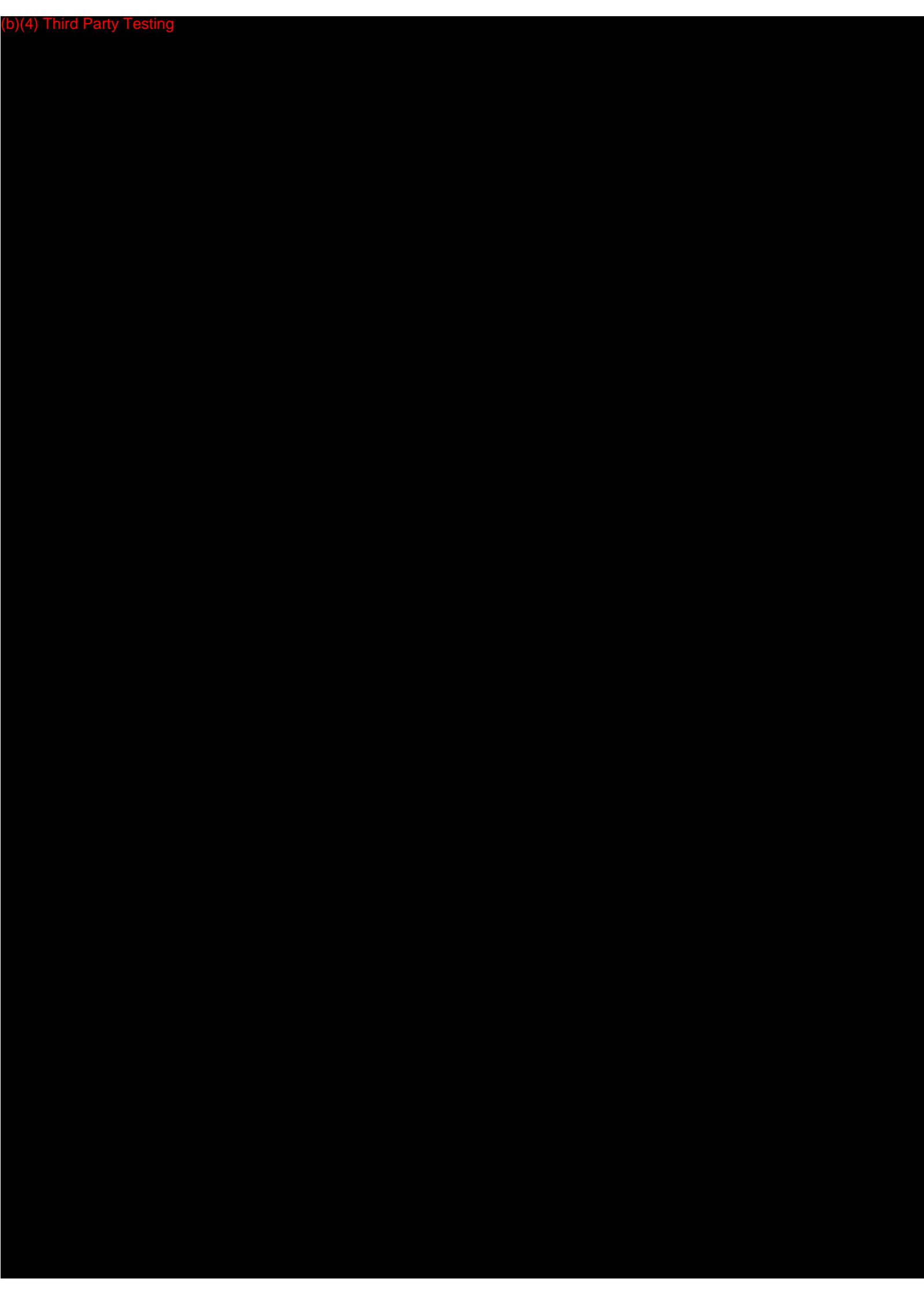
The general transportation means are allowed to be used for the CPAP masks, but the severe shock, vibration and rain and snow shower splash should be prevented in the process of transportation. The transportation standards are required by the orders stipulated in the contract.

3.2 Storage

The packaged masks should be stored in the corrosive gases free, well- ventilated room with $-5^{\circ}\text{C}\sim+50^{\circ}\text{C}$ of the ambient temperature, less than 85% of the relative humidity.







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SECTION 12 Substantial Equivalence Comparisons

1 The general information for predicate device(s)

Product Name1	MIRAGE QUATTRO™ FULL FACE MASK
Sponsor/submitter1	ResMed Limited / Ms. Tracey Bullivant, Regulatory Affairs Manager
Product Name2	ComfortGel Blue Nasal Mask
Sponsor/submitter2	Respironics, Incorporated / Ms. Zita A. Yurko
Attribute	<p>The legally marketed device for comparison is a amendments device; <input type="checkbox"/> Yes; <input checked="" type="checkbox"/> No</p> <p>or the devices which have been granted marketing clearance by FDA following the submission of a 510(k), its K number is K113127 and K092835.</p>

2 The tables for Substantial Equivalence Detailed Comparison

Table 1: Device Comparison Table

	Subject Device:	Predicate Device:	Remarks:
	<p>Device: Skynector CPAP Full-face Mask Manufacturer: Sky Wise Medical Instrument(Shenzhen) Co.,Ltd.</p> <p>510(k) Number: To be determined</p>	<p>Device: Mirage Quattro Full FaceMask Manufacturer: ResMed LTD.</p> <p>510(k) Number: K113127</p>	
<i>Intended Use</i>	<p>The Skynector CPAP Mask channels airflow non-invasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system. The Skynector CPAP Mask is to be used by adult patients (>66lb / >30kg) for whom positive airway pressure has been prescribed. The Skynector CPAP Mask is</p>	<p>The Mirage Quattro channels airflow non-invasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system. The Mirage Quattro is to be used by adult patients (>30 kg) for whom positive airway pressure has been prescribed. The Mirage Quattro is intended for</p>	<p>Both masks are noninvasive and the meanings of intended use are same.</p>

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	Subject Device:	Predicate Device:	Remarks:
	intended for single patient re-use in the home environment and/or multi-patient reuse in the hospital /institutional environment.	single-patient re-use in the home environment and multi-patient re-use in the hospital/institutional environment.	
<i>Patient Population</i>	Patients(>30 kg)	Patients > 66 lbs/30 kg	Same
<i>Environment of use</i>	Home or Hospital/institutional Environment	Home or Hospital/institutional Environment	Same
<i>Product Code</i>	BZD	BZD	Same
<i>Provided Sterile or Non-Sterile</i>	Provided Non-Sterile	Provided Non-Sterile	Same
<i>Patient Usage Type</i>	Single Patient Use in the home or multi-patient use in the hospital/institutional environment.	Single Patient Use in the home or multi-patient use in the hospital/institutional environment.	Same
<i>Design</i>	Face interface and headgear	Face interface and headgear	Same
<i>Material</i>	<p>FM-02: bracket, swivel, connector, elbow: Polycarbonate; forehead pad, cushion, valve: Silicone Rubber; pick off port: Polyvinylchloride; faceplate: Polypropylene; headgear: nylon, polyester.</p> <p>FM-03: bracket, faceplate, swivel, connector, support arm assembly, elbow: Polycarbonate; forehead pad, cushion, valve: Silicone Rubber; pick off port: Polyvinylchloride; headgear: nylon, polyester.</p> <p>FM-05:</p>	Moulded plastic and silicone components and fabric / nylon headgear.	All the materials composed the Skyconnector CPAP masks were evaluated per ISO 10993-1. Based on the testing performed, the differences will not affect the safety or effectiveness of the device.

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	Subject Device:	Predicate Device:	Remarks:
	bracket, faceplate, swivel, connector, support arm assembly, cushion clip, elbow: Polycarbonate; forehead pad, cushion, valve: Silicone Rubber; pick off port: Polyvinylchloride; headgear: nylon, polyester.		
<i>Number of Pick off ports:</i>	One	Two	The design difference will not affect the safety or effectiveness of the device.
<i>Shape and size of faceplate</i>	The shape of the faceplate follows the contours of the face allowing clearance of facial features, covering the mouth and nose for therapy. The faceplate attaches to a silicone cushion via a retaining ring.	The shape of the faceplate and cushion clip offered in various sizes to ensure adequate fit over the extended patient population.	The design difference will not affect the safety or effectiveness of the device.
<i>Shape and size of cushion</i>	The cushions of the FM-02 and FM-05 are made of single layer silicone with damping groove to increase the comfort. The cushion of the FM-03 is made of double layer silicone to increase the comfortable fit.	The previously cleared mask provides characteristics seal via silicone interface. The previously cleared mask offered in various sizes to ensure adequate fit over the extended patient population.	Base on the testing of leakage, the design modification will not affects the safety or effectiveness of the device.
<i>Safety Valve</i>	Contain an anti-asphyxia valve (AAV) to enable the patient to breathe fresh air in the event that airflow from the flow generator is impeded.	Contain an anti-asphyxia valve (AAV) to enable the patient to breathe fresh air in the event that airflow from the flow generator is impeded.	Same
<i>Exhalation device</i>	No accessory exhalation device is required. The full-face masks incorporate intentional vent holes to reduce carbon dioxide re-	No accessory exhalation device is required. The masks incorporate vents to provide continuous air flow to flush out and minimize the amount of CO2 re-breathed by the patient.	Same

Guangzhou Finecure Medical Equipment Co., LTD

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Product: Electrode for Urinary Incontinence

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	Subject Device:	Predicate Device:	Remarks:												
	breathing.														
<i>Anatomical Sites</i>	Mouth and nose	Mouth and nose	Same												
<i>Patient Circuit Connection</i>	22 mm entrainment valve elbow	22 mm entrainment valve elbow	Same												
<i>Pressure Range</i>	4-20 cmH2O	4-40 cmH2O	Verification testing of the modified device did not raise any new questions of safety and efficacy.												
<i>Number of Mask Sizes</i>	FM-02: Three- small, medium, and large FM-03: Three- small, medium, and large FM-05: Three- small, medium, and large	Four- extra small, small, medium, and large	The difference will not affect its function and effectiveness.												
<i>Mask Deadspace</i>	<table border="1"> <thead> <tr> <th>size</th> <th>FM-02 Full-face mask</th> <th>Mirage Quattro Full Face Mask</th> </tr> </thead> <tbody> <tr> <td>L</td> <td>358</td> <td>242</td> </tr> <tr> <td>M</td> <td>311</td> <td>No information available</td> </tr> <tr> <td>S</td> <td>280</td> <td>No information available</td> </tr> </tbody> </table>		size	FM-02 Full-face mask	Mirage Quattro Full Face Mask	L	358	242	M	311	No information available	S	280	No information available	The dead space is calculated by the identical methods. The dead space has no pass/fail criteria, reportable value only. It appears a little larger than the predicate device, but it will not affect its function and effectiveness.
size	FM-02 Full-face mask	Mirage Quattro Full Face Mask													
L	358	242													
M	311	No information available													
S	280	No information available													

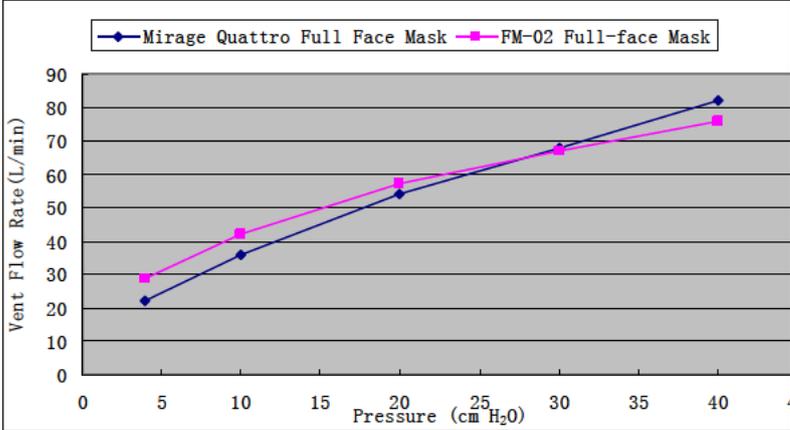
Guangzhou Finecure Medical Equipment Co., LTD

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	Subject Device:	Predicate Device:	Remarks:																		
<i>Leak rate</i>			<p>This leak rate is provided for the healthcare professional to determine if it is compatible with CPAP or bi-level therapy device. It appears the leak rates of CPAP mask is similar with the Mirage Quattro Full Face Mask, leak rate increases stably when air pressure increases.</p>																		
<i>Pressure Drop</i>	<table border="1" data-bbox="443 992 1241 1451"> <thead> <tr> <th colspan="2">Specifications and models</th> <th>Flow (L/min)</th> <th>Drop in Pressure (cmH2O)</th> <th>Mirage Quattro Full Face Mask</th> </tr> </thead> <tbody> <tr> <td rowspan="3">Full-Face mask</td> <td>FM-02L</td> <td>100L/min</td> <td>1.5</td> <td>50L/min</td> </tr> <tr> <td>FM-02M</td> <td>50L/min</td> <td>0.5</td> <td>0.1cmH2O</td> </tr> <tr> <td>FM-02S</td> <td>50L/min</td> <td>0.5</td> <td>100L/min 0.4cmH2O</td> </tr> </tbody> </table>		Specifications and models		Flow (L/min)	Drop in Pressure (cmH2O)	Mirage Quattro Full Face Mask	Full-Face mask	FM-02L	100L/min	1.5	50L/min	FM-02M	50L/min	0.5	0.1cmH2O	FM-02S	50L/min	0.5	100L/min 0.4cmH2O	<p>The pressure drop is measured by the same test configuration. It appears the pressure drop of the CPAP Full-face mask is a little larger than the Mirage Quattro Full Face Mask. The pressure drop is nominal and it will not affect its function and effectiveness.</p>
Specifications and models		Flow (L/min)	Drop in Pressure (cmH2O)	Mirage Quattro Full Face Mask																	
Full-Face mask	FM-02L	100L/min	1.5	50L/min																	
	FM-02M	50L/min	0.5	0.1cmH2O																	
	FM-02S	50L/min	0.5	100L/min 0.4cmH2O																	
<i>Valve Open to Atmosphere</i>	<p>FM-02 Full-Face mask:0.5cmH2O</p>	<p>Mirage Quattro Full Face Mask:1.1cmH2O</p>	<p>The valve will fully open to atmosphere when the mask pressure reaches the opening pressure and remains fully open as the patient inhales and exhales.</p>																		
<i>Valve Close to Atmosphere</i>	<p>FM-02 Full-Face mask:0.8cmH2O</p>	<p>Mirage Quattro Full Face Mask:1.6cmH2O</p>	<p>The valve will fully close to atmosphere when the activation</p>																		

Guangzhou Finecure Medical Equipment Co., LTD (b)(4) (b) Substantial Equivalence
 Product: Electrode for Urinary Incontinence M f t (4) Version (b)(4)

Subject Device:	Predicate Device:	Remarks:
		pressure is met or exceeded.

Table 2: Device Comparison Table

	Subject Device:	Predicate Device:	Remarks:
	Device: Skynector CPAP Nasal Mask Manufacturer: Sky Wise Medical Instrument(Shenzhen) Co.,Ltd. 510(k) Number: To be determined	Device: ComfortGel Nasal Mask Manufacturer: Respironics, Inc. 510(k) Number: K092835	
<i>Intended Use</i>	The reusable CPAP masks with headgear are intended for use as patient interface for a CPAP or bi-level system by adult patients(>30 kg) for whom CPAP or bi-level therapy has been prescribed. The nasal mask covers the nose, and it is to be for single-patient re-use in the home and multi-patient re-use in the hospital/institutional environment.	The ComfortGel Nasal Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The mask is to be used by patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed using a CPAP or bi-level system.	Both masks are noninvasive and the meanings of intended use are same.
<i>Patient Population</i>	Patients(>30 kg)	Patients > 66 lbs/30 kg	Same
<i>Environment of use</i>	Home or Hospital/institutional Environment	Home or Hospital/institutional Environment	Same
<i>Product Code</i>	BZD	BZD	Same
<i>Provided Sterile or Non-Sterile</i>	Provided Non-Sterile	Provided Non-Sterile	Same
<i>Patient Usage Type</i>	Single Patient Use in the home or multi-patient use in the hospital/institutional environment.	Single Patient Use in the home or multi-patient use in the hospital/institutional environment.	Same
<i>Design</i>	Nasal interface and headgear	Nasal interface and headgear	Same

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	Subject Device:	Predicate Device:	Remarks:
<i>Material</i>	<p>NM-01: bracket, faceplate, swivel, support arm assembly, quick clip, elbow: Polycarbonate; forehead pad, cushion: Silicone Rubber; headgear: nylon, polyester; pick off port: Polyvinylchloride.</p> <p>NM-03: bracket, faceplate, swivel, support arm assembly, cushion clip, elbow: Polycarbonate; forehead pad, cushion: Silicone Rubber; headgear: nylon, polyester; pick off port: Polyvinylchloride.</p>	<p>Faceplate: Polycarbonate Face seal: Gel cushion with polyester overlay Cushion Flap: Silicone Exhalation Elbow: Polycarbonate Exhalation Port: Delrin Forehead Pad: Silicone Headgear: UBL, Urethane Foam, and Lycra</p>	<p>All the materials composed the Skynector CPAP masks were evaluated per ISO 10993-1.</p> <p>Based on the testing performed, the modification will not affect the safety or effectiveness of the device.</p>
<i>Number of Pick off ports:</i>	One	None	The design difference will not affect the safety or effectiveness of the device.
<i>Shape and size of faceplate</i>	The shape of the faceplate follows the contours of the face allowing clearance of facial features, covering the nose only for therapy. The faceplate attaches to a silicone cushion via a retaining ring.	The shape of the faceplate follows the contours of the face allowing clearance of facial features, covering the nose only for therapy. The faceplate attaches to a silicone sealing flap via a retaining ring.	Same
<i>Shape and size of cushion</i>	The cushions of the NM-01 and NM-03 are made of double layer silicone to increase the comfortable fit.	Gel cushion to allow for a more comfortable fit and improved mask performance (fewer leaks).	The materials of cushion are different. The design modification will not affect the safety or effectiveness of the device.
<i>Safety Valve</i>	N/A- nasal mask	N/A- nasal mask	Same

Guangzhou Finecure Medical Equipment Co., LTD (b)(4) Substantial Equivalence
 Product: Electrode for Urinary Incontinence M f t i Version (b)(4)

Subject Device:	Predicate Device:	Remarks:													
<i>Exhalation device</i>	No accessory exhalation device is required. An exhalation vent is integrated.	No accessory exhalation device is required. 54 pin holes exhalation ports are integrated.	Based on the testing performed, the design difference will not affect the safety or effectiveness of the device.												
<i>Anatomical Sites</i>	Nose	Nose	Same												
<i>Patient Circuit Connection</i>	22 mm exhalation elbow	22 mm exhalation elbow	Same												
<i>Pressure Range</i>	4-20 cmH2O	4-30 cmH2O	Verification testing of the modified device did not raise any new questions of safety and efficacy.												
<i>Number of Mask Sizes</i>	NM-01: Four- petite, small, medium, and large; NM-03: Three- small, medium, and large.	Four- petite, small, medium, and large	The difference will not affect its function and effectiveness.												
<i>Mask Deadspace</i>	<table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>size</th> <th>NM-03 nasal mask</th> <th>The ComfortGel Nasal Mask</th> </tr> </thead> <tbody> <tr> <td>L</td> <td>180</td> <td>142.6</td> </tr> <tr> <td>M</td> <td>160</td> <td>121.3</td> </tr> <tr> <td>S</td> <td>150</td> <td>111.4</td> </tr> </tbody> </table>	size	NM-03 nasal mask	The ComfortGel Nasal Mask	L	180	142.6	M	160	121.3	S	150	111.4		The dead space is calculated by the identical methods. The dead space has no pass/fail criteria, reportable value only. It appears a little larger than the predicate device, but it will not affect its function and effectiveness.
size	NM-03 nasal mask	The ComfortGel Nasal Mask													
L	180	142.6													
M	160	121.3													
S	150	111.4													
<i>Leak rate</i>			This leak rate is provided for the healthcare professional to determine if it is compatible with CPAP or bi-level therapy device. It appears the leak rates of CPAP mask												

Guangzhou Finecure Medical Equipment Co., LTD

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	Subject Device:	Predicate Device:	Remarks:																			
	<table border="1"> <caption>Approximate data from Vent Leak Rate graph</caption> <thead> <tr> <th>Pressure (cm H₂O)</th> <th>ComfortGel Nasal Mask (L/min)</th> <th>NM-03 Nasal Mask (L/min)</th> </tr> </thead> <tbody> <tr> <td>5</td> <td>18</td> <td>18</td> </tr> <tr> <td>10</td> <td>28</td> <td>28</td> </tr> <tr> <td>20</td> <td>38</td> <td>40</td> </tr> <tr> <td>30</td> <td>48</td> <td>48</td> </tr> <tr> <td>40</td> <td>52</td> <td>55</td> </tr> </tbody> </table>		Pressure (cm H ₂ O)	ComfortGel Nasal Mask (L/min)	NM-03 Nasal Mask (L/min)	5	18	18	10	28	28	20	38	40	30	48	48	40	52	55	is similar with the ComfortGel Nasal Mask, leak rate increases stably when air pressure increases.	
Pressure (cm H ₂ O)	ComfortGel Nasal Mask (L/min)	NM-03 Nasal Mask (L/min)																				
5	18	18																				
10	28	28																				
20	38	40																				
30	48	48																				
40	52	55																				
Pressure Drop	<table border="1"> <thead> <tr> <th>Specifications and models</th> <th>Flow (L/min)</th> <th>Drop in Pressure (cmH₂O)</th> <th>ComfortGel Nasal Mask</th> </tr> </thead> <tbody> <tr> <td rowspan="2">Nasal mask</td> <td>NM-03L</td> <td rowspan="2">100L/min</td> <td rowspan="2">0.3</td> <td>50L/min</td> </tr> <tr> <td>NM-03M</td> <td>0.1cmH₂O</td> </tr> <tr> <td rowspan="2"></td> <td>NM-03S</td> <td rowspan="2">50L/min</td> <td rowspan="2">0.1</td> <td>100L/min</td> </tr> <tr> <td></td> <td>0.25cmH₂O</td> </tr> </tbody> </table>			Specifications and models	Flow (L/min)	Drop in Pressure (cmH ₂ O)	ComfortGel Nasal Mask	Nasal mask	NM-03L	100L/min	0.3	50L/min	NM-03M	0.1cmH ₂ O		NM-03S	50L/min	0.1	100L/min		0.25cmH ₂ O	The pressure drop is measured by the same test configuration. It appears the pressure drop of the CPAP Nasal mask is a little larger than the ComfortGel Nasal Mask. The pressure drop is nominal and it will not affect its function and effectiveness.
	Specifications and models	Flow (L/min)	Drop in Pressure (cmH ₂ O)	ComfortGel Nasal Mask																		
Nasal mask	NM-03L	100L/min	0.3	50L/min																		
	NM-03M			0.1cmH ₂ O																		
	NM-03S	50L/min	0.1	100L/min																		
				0.25cmH ₂ O																		
Valve Open to Atmosphere	N/A- nasal mask	N/A- nasal mask	Same																			
Valve Close to Atmosphere	N/A- nasal mask	N/A- nasal mask	Same																			

3 The discussion of the similarities and differences

The discussion of the similarities with and differences between subject device and predicate device were described in column "Remarks" in previous table 1 and table 2, the discussion demonstrate that the differences did not arise new safety issues.

Guangzhou Finecure Medical Equipment Co., LTD	(b)(4)	Substantial Equivalence
Product: Electrode for Urinary Incontinence	M f t i	Version (b)(4)

4 Final Conclusions

The subject devices have all features of the predicate device. The few differences do not affect the safety and effectiveness of the subject devices.

Thus, the subject devices are substantially equivalent to the predicate device.

JAN - 6 2012

RESMED

Mirage Quattro
Special 510(k): Device Modification

5. 510(k) SUMMARY

k 113127

[As required by 21 CFR 807.92]

Date Prepared 18 October, 2011

Submitter Ms. Tracey Bullivant,
Regulatory Affairs Manager

Official Contact Mr. David D'Cruz,
V.P., US Medical & Regulatory Affairs
9001 Spectrum Center Blvd
San Diego CA 92123 USA
Tel: (858) 836-5984

Device Trade Name Mirage Quattro™

Device Common Name/ Classification Name Vented Full Face Mask;
Accessory to Noncontinuous Ventilator (IPPB)

Classification 21 CFR 868.5905, 73 BZD (Class II)

Predicate Device Mirage Quattro™ (K063122)

Description The Mirage Quattro provides an interface such that airflow from a positive pressure source is directed to the patient's nose and mouth. The mask is held in place with adjustable headgear that straps the mask to the face.

The Mirage Quattro is safe when used under the conditions and purposes intended as indicated in the labeling provided with the product.

The Mirage Quattro is a prescription device supplied non-sterile.

Intended Use The Mirage Quattro channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bilevel system.

The Mirage Quattro is to be used by adult patients (>66lb / >30kg) for whom positive airway pressure has been prescribed.

The Mirage Quattro is intended for single patient re-use in the home environment and/or multi-patient reuse in the hospital/institutional environment.

RESMED

Mirage Quattro
Special 510(k): Device Modification

Comparison of Technological Characteristics

Comparison with previously cleared Mirage Quattro

The modified device and the previously cleared mask both provide a seal via silicone interface. Both masks are offered in various sizes to ensure adequate fit over the extended patient population.

Both masks incorporate vents to provide continuous air flow to flush out and minimize the amount of CO₂ rebreathed by the patient. The design of the mask components is such that the incorporation of these vents does not interfere with the intended performance of the masks. Both masks also contain an anti-asphyxia valve (AAV) to enable the patient to breathe fresh air in the event that airflow from the flow generator is impeded.

Both masks connect to a conventional air delivery hose between the mask and the positive airway-pressure source via standard conical connectors (ref. ISO 5356-1:2004).

Both masks are constructed using moulded plastic and silicone components and fabric / nylon headgear. All the components of both masks are fabricated using materials deemed safe (ISO10993-1).

Both the modified device and the previously cleared device are designed to operate on the same *Full Face ResMed* flow generator settings. The pressure-flow characteristics and flow impedance of both the modified device and the predicate device are identical.

Both the modified device and the previously cleared device can be reused in the home and hospital / institution environment.

Clinical Data

Use of vented masks with CPAP or Bilevel therapy is proven technology and is well accepted by the medical community. Bench testing is sufficient to demonstrate safety and efficacy of the modified Mirage Quattro, as was the case with the previously cleared Mirage Quattro device.

Performance Data

Comparison with previously cleared Mirage Quattro

The CO₂ performance of the modified device and the previously cleared device are substantially equivalent. Both the modified device and the previously cleared device are designed to operate on the same flow generator settings as specified in the User Guide. The only difference is an extension in the therapy pressure range from 4-20cmH₂O to 4-40cmH₂O. Verification testing of the modified device did not raise any new questions of safety and efficacy.

Substantial Equivalence Conclusion

The modified Mirage Quattro is as safe and effective as the previously cleared Mirage Quattro device:

- it has the same intended use;
- it has identical technological characteristics to the previously cleared device;
- the modified device did not raise any new questions of safety or effectiveness;
- it is at least as safe and effective as the previously Cleared Mirage Quattro (K063122).



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

JAN - 6 2012

ResMed Limited
C/O Mr. David D'Cruz
Vice President, US Medical Regulatory Affairs
ResMed Corporation
9001 Spectrum Center Boulevard
San Diego, California 92123

Re: K113127
Trade/Device Name: MIRAGE QUATTRO™ FULL FACE MASK
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: December 2, 2011
Received: December 7, 2011

Dear Mr. D'Cruz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2- Mr. D'Cruz

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

RESMED

Mirage Quattro
Special 510(k): Device Modification

Indications for Use

510(k) Number (if known):

Device Name: MIRAGE QUATTRO™ FULL FACE MASK

Indication for Use

The Mirage Quattro channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bilevel system.

The Mirage Quattro is to be used by adult patients (>66lb / >30kg) for whom positive airway pressure has been prescribed.

The Mirage Quattro is intended for single patient re-use in the home environment and/or multi-patient reuse in the hospital/institutional environment.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

Page 1 of 1



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113127

TAB 3

K092835
page 1 of 7

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

Original Date of Submission	14 September 2009	FEB 12 2010
Device Trade Name	ComfortGel Blue Nasal Mask	
Common/Usual Name	Ventilator, non-continuous (respirator)	
Establishment Registration #	2518422	
Address of Mfr. Facility	Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 (724) 387-4120	
Classification	Class II device	
Classification Panel	Anesthesiology Devices	
Classification Reference	21 CFR 868.5905	
Product Code	BZD – Ventilator, non-continuous (respirator)	
Predicate Device(s)	Respironics ComfortGel Full Face Mask (K073600) Respironics Reusable Contour II Nasal Mask (K991648)	
Labeling	Draft Labeling can be found in Tab 5.	
Intended Use	The ComfortGel Blue Nasal Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The mask is to be used by patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed.	
Reason for Submission	Modify the ComfortGel Full Face Mask to provide a nasal mask offering with a gel cushion.	

Intended Use

The ComfortGel Blue Nasal Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The mask is to be used by patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed.

Device Description

The Respironics ComfortGel Blue Nasal Mask consists of a polycarbonate faceplate with a gel cushion encapsulated in a polyester seal for the face. The mask includes integrated exhalation features on the elbow. It is an accessory for use with CPAP and bi-level devices in the home (single patient use) and hospital/institution (multi-patient use).

The ComfortGel Blue Nasal mask covers the patient's nose only. It is strapped to the patient's face using headgear which connects to the mask via slots in the forehead bracket at the top, and via ball clip headgear attachments, which fit into sockets in the mask faceplate at the bottom. The mask is connected to the CPAP or bi-level flow generator via standard 22mm patient tubing. Positive pressure ventilation is then able to be applied to the lungs in a non-invasive way.

Substantial Equivalence

The ComfortGel Blue Nasal Mask has the following similarities to the previously cleared predicate devices:

- Same intended use.
- Same operating principle.
- Same technology.
- Same manufacturing process.

There is no change to the intended use, operating principle, technology or manufacturing process for the ComfortGel Blue nasal mask. Design modifications were made to the previously cleared ComfortGel Full Face Mask (K073600) to provide a nasal mask offering, similar to the Reusable Contour II Nasal Mask, with a gel cushion. The following changes have been made:

1. Modification to the mask materials
2. Removal of pressure pick-off port.
3. Modification to match mask dimensions to that of a nasal mask

4. Modification to the mask elbow to remove entrainment valve, similar to the Reusable Contour II Nasal Mask (K991648).
5. Modification to add additional sizes of the mask.
6. Modification to the mask deadspace.

Table 1 provides a detailed technology and performance comparison for the ComfortGel Blue Nasal Mask to the cited device predicates Reusable Contour II Nasal Mask (K991648) and ComfortGel Full Face Mask (K073600). Differences from the predicate devices are noted by the shaded areas.

Table 1: Device Comparison Table

	<u>Subject Device:</u>	<u>Predicate Device:</u>	<u>Subject Device:</u>
	Device: Respironics ComfortGel Full Face Mask Manufacturer: Respironics, Inc. 510(k) Number: K073600	Device: Respironics Reusable Contour II Nasal Mask Manufacturer: Respironics, Inc. 510(k) Number: K991648	Device: Respironics ComfortGel Nasal Mask Manufacturer: Respironics, Inc. 510(k) Number: To be determined
<i>Intended Use</i>	The ComfortGel Full Face Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for multi-patient use in the home or hospital/institutional environment. The mask is intended to be used on patients (>66 lbs/30kg) for whom CPAP or bi-level therapy has been prescribed using a CPAP or bi-level system.	The Respironics Reusable Contour II Nasal Mask is intended to provide an interface for application of Respironics bi-level or CPAP therapy to patients. For single patient use in the home or hospital/institutional environment. The mask is to be used on adult patients (>30kg) for who bi-level or CPAP therapy has been prescribed using a Respironics bi-level or CPAP system.	The ComfortGel Nasal Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The mask is intended to be used on patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed using a CPAP or bi-level system.
<i>Patient Population</i>	Patients > 66 lbs/30 kg	Patients >30kg	Unchanged from K073600/K991648
<i>Environment of Use</i>	Home or Hospital/institutional Environment	Home or Hospital/Institutional Environment	Unchanged from K073600/K991648
<i>Product Code</i>	BZD	BZD	Unchanged from K073600/K991648
<i>Provided Sterile or Non-Sterile</i>	Provided clean, not sterile	Provided clean, not sterile	Unchanged from K073600/K991648
<i>Patient Usage Type</i>	Multi-patient Use	Single patient use	Single Patient Use in the home or multi-patient use in the hospital/institutional environment.
<i>Design</i>	Face interface and headgear	Nasal interface and headgear	Unchanged from K991648
<i>Materials</i>	Faceplate: Polycarbonate Face Seal: gel cushion	Faceplate: Polycarbonate	Faceplate: Polycarbonate Face seal: Gel cushion

	with urethane overlay Cushion flap: Silicone Exhalation Port: Polycarbonate Entrainment Valve: Polycarbonate with Silicone Flapper Headgear: UBL, Urethane foam and lycra	Face Seal: Silicone Cushion Exhalation Elbow: Polycarbonate Headgear: Velstretch/Lycra laminated foam	with polyester overlay Cushion Flap: Silicone Exhalation Elbow: Polycarbonate Exhalation Port: Delrin Forehead Pad: Silicone Headgear: UBL, Urethane Foam, and Lycra
<i>Number of Pressure Pickoff ports</i>	One	One	None
<i>Shape and size of faceplate</i>	The shape of the faceplate follows the contours of the face allowing clearance of facial features, covering the nose and mouth for therapy. The faceplate attaches to a silicone sealing flap via a retaining ring.	Profile of the faceplate is streamlined for a slightly flatter, rounder and more complete shape to help reduce mask volume.	The shape of the faceplate follows the contours of the face allowing clearance of facial features, covering the nose only for therapy. The faceplate attaches to a silicone sealing flap via a retaining ring.
<i>Shape and size of cushion</i>	Gel cushion to allow for a more comfortable fit and improved mask performance (less leak).	Cushion varies in thickness for better seal and easier fit. The cushion material is thinnest where the cushion contacts the user's nose. Thin cushion material allows three basic mask sizes to fit a broad range of facial features.	Gel cushion to allow for a more comfortable fit and improved mask performance (less leak). Dimensions modified to fit nasal mask.
<i>Safety Valve</i>	The safety valve is integral to the mask.	N/A- nasal mask	Unchanged from K991648
<i>Exhalation device</i>	No accessory exhalation device is required. Exhalation ports are integrated	No accessory exhalation device is required. Exhalation ports are integrated	No accessory exhalation device is required. 54 pin hole exhalation ports are integrated
<i>Anatomical Sites</i>	Nose & mouth	Nose	Unchanged from K991648
<i>Patient Circuit Connection</i>	22 mm entrainment valve elbow	22 mm exhalation elbow	Unchanged from K991648
<i>Pressure Range</i>	4 to 30 cmH2O	4 to 30 cmH2O	Unchanged from K073600/K991648
<i>Number of Mask Sizes</i>	Three – small, medium and large	Three – small, medium and large	Four- petite, small, medium, and large
<i>Mask Deadspace</i>	Small – 210 cc Medium – 260 cc Large – 300 cc	Small: ~95 cc Medium: ~123 cc Large: ~123 cc	Petite: 76 cc Small: 97 cc Medium: 99 cc Large: 118 cc
<i>Intentional Leak</i>	> 9.5 SLPM @ 2.5 cm	≥ 7.5 SLPM @ 1.5 cm H2O	Unchanged from K073600

	H2O > 15 SLPM @ 5 cm H2O < 64 SLPM @ 40 cm H2O	≥ 10 SLPM @ 2.5 cm H2O ≥ 16 SLPM @ 5.0 cm H2O ≤ 67 SLPM @ 40 cm H2O	
<i>Unintentional Leak</i>	≤17 SLPM @20 cm H2O ≤ 28 SLPM @ 35 cm H2O	≤17 SLPM @20 cm H2O ≤ 28 SLPM @ 35 cm H2O	Unchanged from K073600/K991648
<i>Pressure Drop</i>	Closed to Atmosphere: ≤ 1 cm H2O at flows ≤ 50 SLPM ≤ 4 cm H2O at flows ≤ 100 SLPM Open to Atmosphere: ≤ 2 cm H2O @ flow up 60 lpm	Not known	< 1 cmH2O (.98 hPa) at flows ≤ 50 SLPM < 4 cmH2O (3.9 hPa) at flows ≤ 100 SLPM (Elbow without entrainment valve comparable to Elbow with entrainment valve, closed to atmosphere.)
<i>Valve Open to Atmosphere</i>	PAP Pressure ≥ 1cm H2O (0.40 in H2O) and ≤ 3 cm H2O (1.2 in H2O)	N/A- nasal mask	Unchanged from K991648
<i>Valve Close to Atmosphere</i>	PAP Pressure ≥ - 1 cm H2O (-0.40 in H2O)	N/A- nasal mask	Unchanged from K991648
<i>Mask Weight</i>	Small: 5.24 oz. Medium: 5.54 oz. Large: 5.86 oz.	No information available	Petite: ~4.83 oz. Small: ~ 5.39 oz. Medium:~ 5.28 oz. Large: ~ 5.45 oz.
<i>Cushion Height, Length and Width</i>	Small: 4.01" x 3.51" x 1.73" Medium: 4.34" x 3.84" x 1.72" Large: 4.78" x 3.84" x 1.74"	No information available	Petite: 2.26" x 2.45" x 1.47" Small: 2.76" x 2.78" x 1.47" Medium: 2.76" x 2.78" x 1.49" Large: 3.16" x 2.84" x 1.47"
<i>Faceplate Height, Length and Width</i>	Small: 4.82" x 4.00" x 1.09" Medium: 5.03" x 4.32" x	No information available	Petite: 3.25" x 3.25" x 0.97" Small/Medium: 3.62" x

	1.09" Large: 5.47" x 4.32" x 1.09"		3.38" x 0.97" Large: 3.90" x 3.52" x 0.97"
<i>Occluded End Tidal CO2</i>	Small = 7.6% Medium = 6.9% Large = 6.7%	No information available	Large = 7.9%

To demonstrate performance and functionality of the ComfortGel Blue Nasal Mask was unaffected as a result of these changes, extensive performance testing, to include intentional leak, unintentional leak, pressure drop, CO2 rebreathing, deadspace testing and swivel torque was completed on both untreated and treated samples. Testing was performed pre and post home/clinical cleaning and disinfection treatments. Additionally, efficacy testing was performed to ensure that the mask could be high level disinfected to assure a minimum of a 6 log reductions for this mask as tested in accordance with AAMI TIR No. 12-2004, AAMI TIR 30-2003, ANSI/AAMI/ISO 14937-2000, and the "content and format of Premarket notification submissions for liquid chemical sterilants/high level disinfectants" – FDA CDRH, January 3, 2000. Results from this testing concluded that the verification testing raises no new issues of safety or effectiveness.

Respiroics has followed the FDA's Guidance for Industry and FDA Staff document "pre-market assessment of pediatric medical devices" and applied the principle of FDA's Least Burdensome Approach to demonstrate the Substantial Equivalence of the ComfortGel Blue Nasal Mask. As a result we conclude that the existing indications for use can be safely and effectively applied to this device.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

FEB 12 2010

Respironics, Incorporated
Ms. Zita A. Yurko
Director, Regulatory Affairs
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668

Re: K092835
Trade/Device Name: ComfortGel Blue Nasal Mask
Regulation Number: 21CFR 868.5905
Regulation Name: Noncontinuous Ventilator IPPB
Regulatory Class: II
Product Code: BZD
Dated: January 18, 2010
Received: February 2, 2010

Dear Ms. Yurko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2- Ms. Yurko

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Page 1 of 1

Indications for Use

510(k) Number (if known): _____

Device Name: ComfortGel Blue Nasal Mask

The ComfortGel Blue Nasal Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The mask is to be used by patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092835



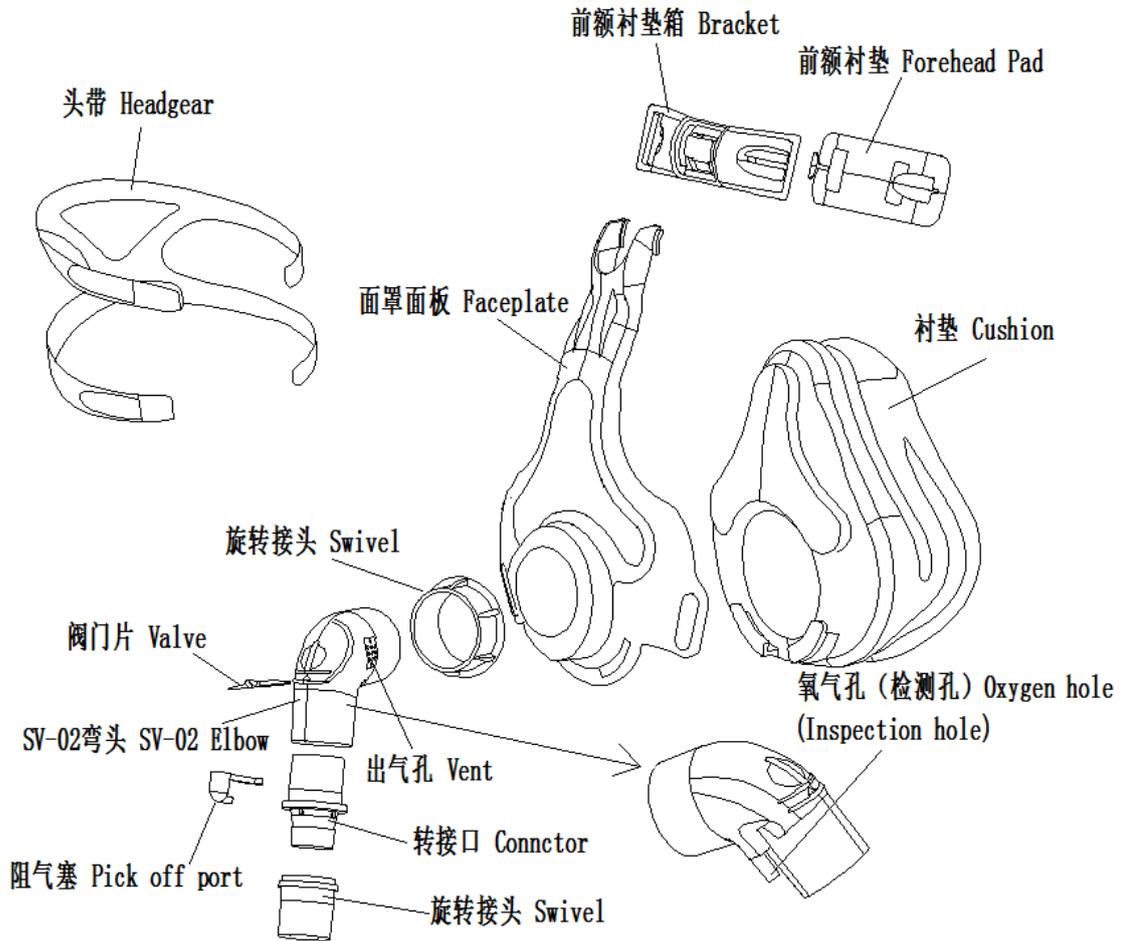
Instruction For Use

FM-02 Series CPAP Full-Face Mask

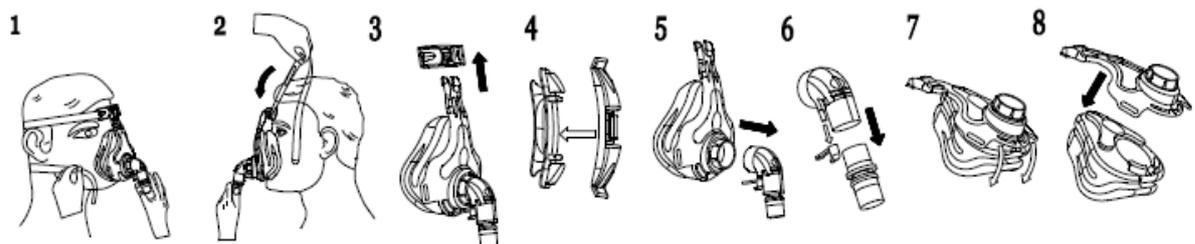
User Guide

English

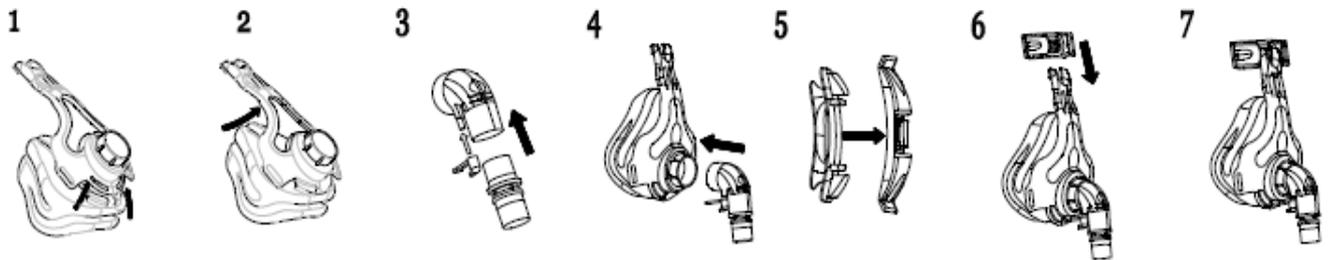
A Structure Description



B Disassembling for cleaning



C Reassembling the mask



Skynector CPAP

FM-02 Full-Face Mask

Thank you for choosing Skynector CPAP Full-Face Mask.

The Skynector CPAP Full-Face Mask is a system that covers your nose and mouth. This means that you can receive effective therapy even if you breathe through your mouth. The mask incorporates vent holes and a built-in valve so that you can continue to breathe fresh air if the airflow to your mask is impeded for any reason.

Intended Use/Indications for Use

The Skynector CPAP Mask channels airflow non-invasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system.

The Skynector CPAP Mask is to be used by adult patients (>66lb / >30kg) for whom positive airway pressure has been prescribed.

The Skynector CPAP Mask is intended for single patient re-use in the home environment and/or multi-patient reuse in the hospital /institutional environment.

Before Using the Mask

WARNINGS

1. This mask is not suitable for providing life support ventilation.
2. This mask is designed for use with CPAP or Bi-level systems recommended by your health care professional or respiratory therapist. Do not wear this mask unless the

CPAP or Bi-level system is turned on and operating properly. Do not block or try to seal the vent holes.

Explanation of the Warning: CPAP systems are intended to be used with special masks with connectors which have vent holes to allow continuous flow of air out of the mask. When the CPAP machine is turned on and functioning properly, new air from the CPAP machine flushes the exhaled air out through the attached mask exhalation port. However, when the CPAP machine is not operating, enough fresh air will not be provided through the mask, and exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can in some circumstances lead to suffocation. This warning applies to most models of CPAP systems.

3. If oxygen is used with the device, the oxygen flow must be turned off when the device is not operating. Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.
4. At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, mask selection, and the leak rate. This warning applies to most types of CPAP and Bi-level machines.
5. At low CPAP pressures the flow through the vent holes may be inadequate to clear all exhaled gas from the tubing. Some rebreathing may occur.
6. This product may contain chemicals (phthalates) which may cause adverse reactions for the patients who are pregnant or lactational. Consult the health care professional before use.
7. Some users may experience skin redness, irritation, or discomfort. If this happens, discontinue use and contact your health care professional.
8. The patient's physician should be contacted if the patient experiences the following symptoms while using the mask or after removing it: Unusual chest discomfort, shortness of breath, stomach distension, belching, or severe headache; drying of the eyes, eye pain, or eye infections; blurred vision.(Consult an ophthalmologist if symptoms persist).
9. A minimum of 3cm H₂O (HPa) must be maintained when using this mask.
10. This mask is not recommended for patients who are taking a prescription drug that may cause vomiting.
- 11.Using a mask may cause tooth, gum, or jaw soreness or aggravate an existing dental condition. Consult your physician or dentist if symptoms occur.

Caution:

1. Do not use if the package is damaged.
2. Read and understand the instructions completely.
3. The mask is supplied as non-sterile. The mask needs to be washed with drinking quality water before first use.
4. Wash patient's face before use.

5. Check the size of the mask and the headgear.
6. The connector of this mask is conical 22mm and complies with the ISO 5356 standard. Check whether the outlet of the oxygen machine matches the mask before use.
7. Dispose of mask in accordance with local regulations.

Contraindications:

The masks should not be used if the patient is unresponsive or unable to remove the mask by themselves, and it is not recommended for patients who are taking a prescription drug that may cause vomiting.

Side effects:

Some users may experience skin redness, irritation, or discomfort. Some users may experience unusual chest discomfort, shortness of breath, stomach distension, belching, or severe headache; drying of the eyes, eye pain, or eye infections; blurred vision.

Disassembling the Mask:

See section B on the illustrations sheet.

1. Unclip the lower headgear velcro (Fig.B-1).
2. Unclip the upper headgear velcro (Fig.B-2).
3. Press the top faceplate, remove the bracket from the faceplate(Fig.B-3).
4. Remove the forehead pad from the bracket(Fig.B-4).
5. Remove the connector from the mask faceplate(Fig.B-5).It's easier to pivot the bottom of the connector away from the mask faceplate than to pull the connector straight off.
6. Detach the swivel from the elbow(Fig.B-6).
7. Squeeze and push the upper side tabs on the cushion out of the faceplate(Fig.B-7). Pivot away from the faceplate, and gently pull out.
8. Separate the cushion from the faceplate. (Fig.B-8).

Cleaning of the CPAP mask

Daily/After Each use:

For the non-sterile mask or reuse mask, it need a hand wash prior to first use or daily, and the headgear should be hand washed weekly or when needed. The cleaning instruction is as below:

1. Cleaning the pick off port with a soft bristle brush for 1 minute while soaking in the detergent, Alconox (diluted 1%), paying particular attention to crevices and cavities. Caution: Do not use bleach, alcohol, cleaning solutions containing bleach or alcohol, or cleaning solutions containing conditioners or moisturizers.
2. Rinse thoroughly with drinking quality water(5 liters per mask) three times until clean and air dry out of direct sunlight. Make sure the mask is dry before use. Lay the headgear flat or line dry. Do not place the headgear into the dryer.
3. Inspect the mask. If any parts are damaged or can not be cleaned, replace the mask.

High Level Disinfection of the Mask between Patients

All mask components can be disinfected using validated procedures. The following presents a summary of the validated procedures for disinfection of the system. Refer to the website www.skynector.com for details or contacting Skywise Customer Service at +86 (0)755 28494331.

The CPAP mask		Sky Wise validated disinfection procedures		Validated number of cycles
		High level thermal disinfection	High level chemical disinfection	
		EN ISO 15883-1 75°C - 30min	Glutaraldehyde 3.4% for 20 minutes	
Full-face	FM-02	✓	✓	15

High level thermal disinfection instruction is as below:

1. Using a certified hot water disinfection system, soak the mask components using a temperature-time combination:

EN ISO 15883-1:

- 75°C for 30minutes
2. Remove the mask components from the hot water disinfection system.
 3. Air dry out of direct sunlight.

High level chemical disinfection instruction is as below:

1. Soak the mask components in glutaraldehyde 3.4% for 20 minutes.
2. Rinse thoroughly with drinking quality water(5 liters per mask) three times and air dry out of direct sunlight.

Inspection : Perform a visual inspection of each mask component. If any visible deterioration of a mask component is apparent (cracking, crazing, tears etc), the mask component should be discarded and replaced. Slight discolouration of the silicone components may occur and is acceptable.

Caution: The Mask must be thoroughly cleaned prior to high level disinfection.

Reassembling the Mask

See section C on the illustrations sheet.

Before reassembling the mask, check that all components are clean and dry. Check that the valve is not damaged, distorted or torn, and that none of the other components are broken or cracked. Replace any parts that are damaged.

1. Insert the upper side tabs on the lower cushion into the faceplate(Fig.C-1).
Insert the upper cushion into the faceplate(Fig.C-2).Ensure that the cushion is not twisted or distorted.
2. Insert the swivel into the end of the elbow(Fig.C-3).
3. Insert the assembled connector into the mask faceplate(Fig.C-4).
4. Insert the forehead pad into the bracket(Fig.C-5).
5. Press the top faceplate, insert the bracket into the faceplate(Fig.C-6).

Directions for Use:

1. Make sure the mask is within the expiration date. Tear the package and take out the mask.
2. Cover the mask on the patient's face and fasten with the headgear.
3. Connect the oxygen hose to the oxygen supply.

Wearing Methods:

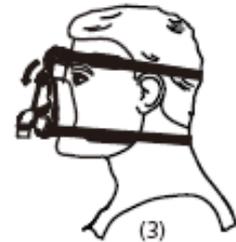
1. Connect the headgear to the mask. Position the mask over your face, and press the mask cushion gently against your face, pull the headgear over your head.



2. Adjust the top and the bottom straps so that the mask is sitting gently on your face.



3. Fasten the mask.



Technical parameters:

Deliverable pressure range :4~20 cmH₂O

Pressure Drop cm H₂O (hPa):

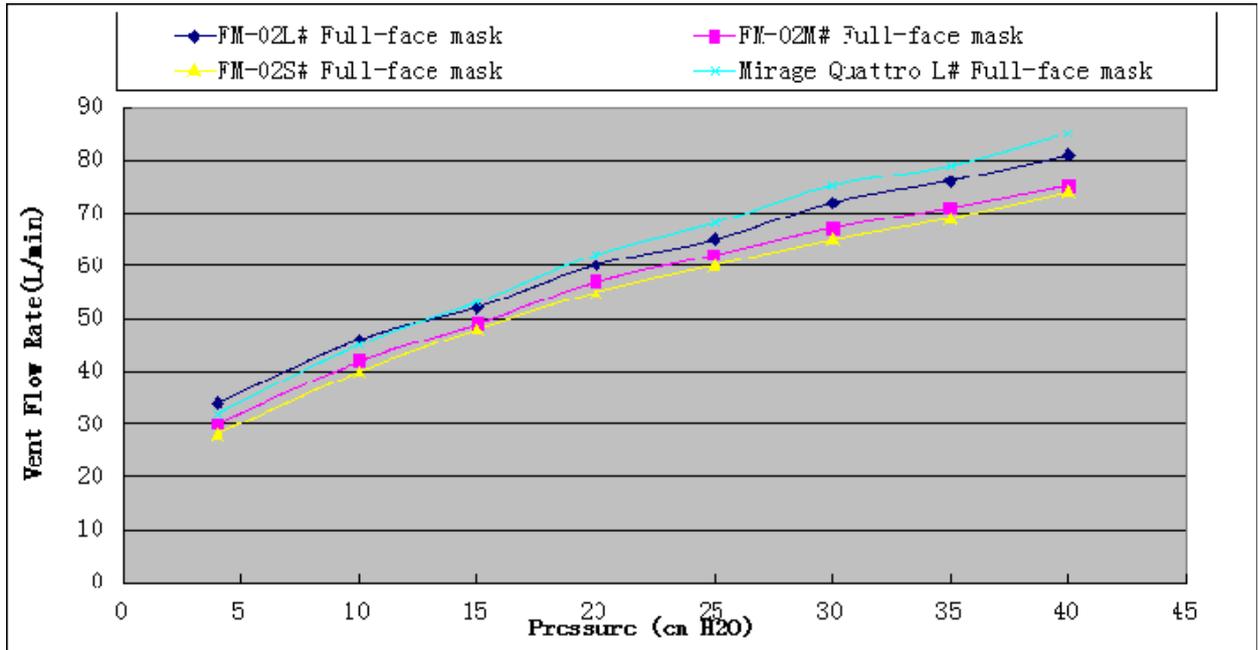
All mask size: 50 SLPM 0.5

100 SLPM 1.5

Deadspace Volume

FM-02L: 358mL; FM-02M: 311mL; FM-02S: 280mL

Pressure-flow curve



Open/close pressure for anti-asphyxia valve (cmH₂O):

Open pressure:2.0 close pressure:1.5

Storage

The packaged masks should be stored in the corrosive gases free, well- ventilated room with -5°C~+50°C of the ambient temperature, less than 85% of the relative humidity.

Mask sizes

Size	length(mm)	width(mm)	height(mm)
L	215	120.5	130
M	215	115.5	130
S	215	115.5	126

Manufacturer: Sky Wise Medical Instrument (Shenzhen) Co., Ltd.

Address: No 12 South Ping Xi Road Xinsheng Community, Longgang Street, Longgang District, Shenzhen, Guangdnog, China

Contact person: Hu hanhan
 TEL: +86-755-28491103
 FAX: +86-755-28494339
 E-Mail: 942526346@qq.com



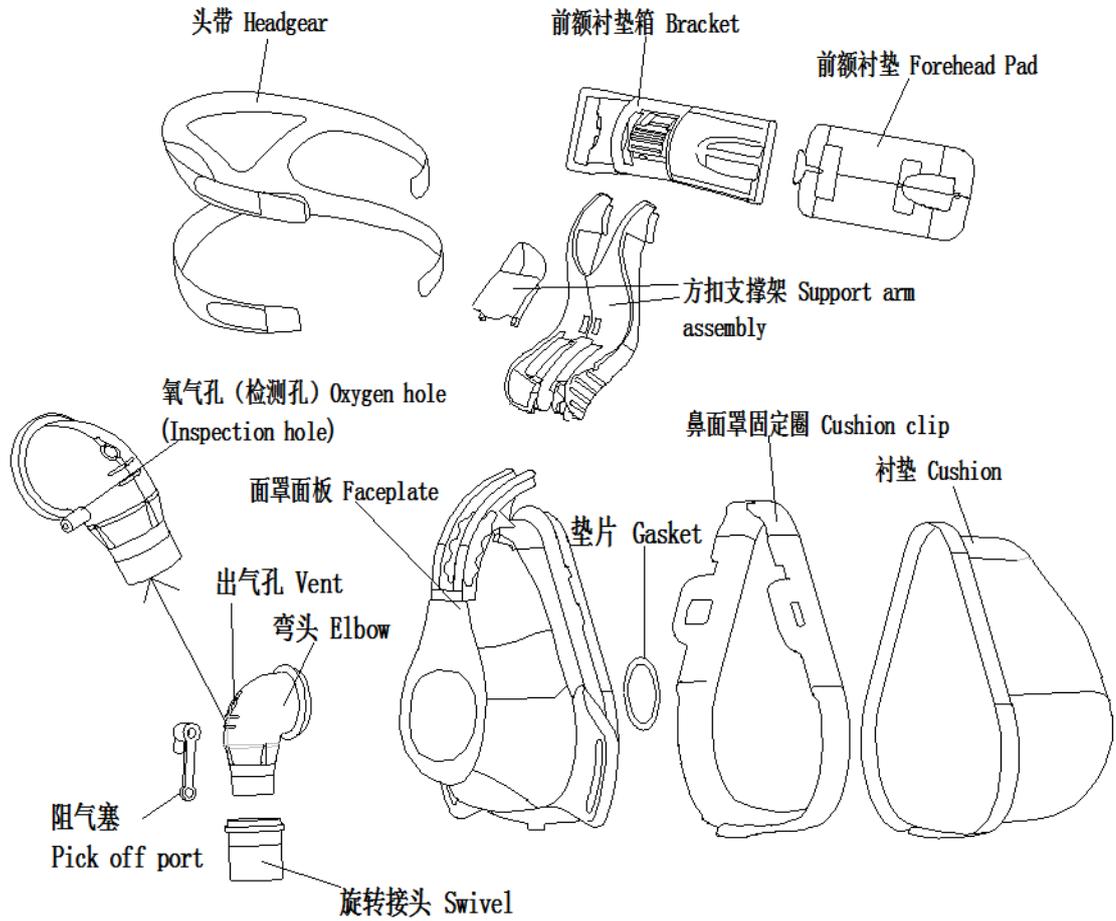
Instruction For Use

NM-03 Series CPAP Nasal Mask

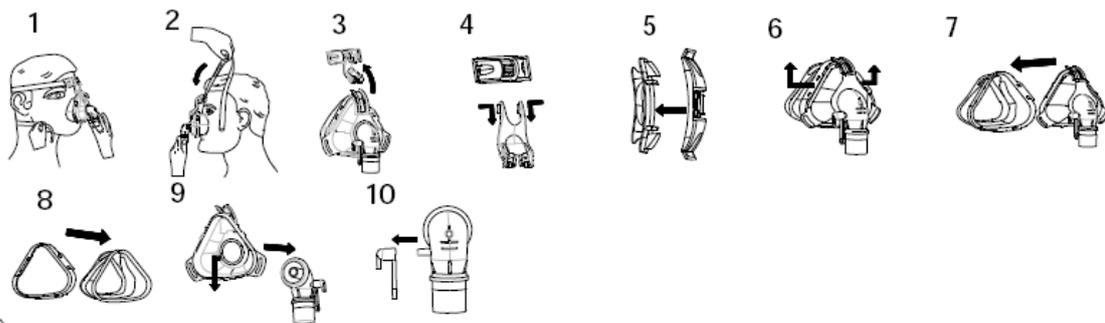
User Guide

English

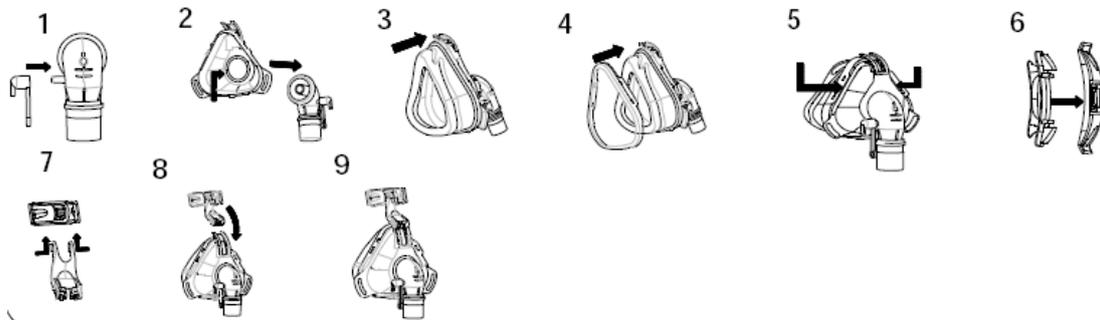
A Structure Description



B Disassembling for cleaning



C Reassembling the mask



Skynector CPAP

NM-03 Nasal Mask

Thank you for choosing Skynector CPAP Nasal Mask.

The Skynector CPAP Nasal Mask is a system that covers your nose only. The mask incorporates vent holes to reduce carbon dioxide rebreathing.

Intended Use/Indications for Use

The Skynector CPAP Mask channels airflow non-invasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system.

The Skynector CPAP Mask is to be used by adult patients (>66lb / >30kg) for whom positive airway pressure has been prescribed.

The Skynector CPAP Mask is intended for single patient re-use in the home environment and/or multi-patient reuse in the hospital /institutional environment.

Before Using the Mask



WARNINGS

1. This mask is not suitable for providing life support ventilation.
2. This mask is designed for use with CPAP or Bi-level systems recommended by your health care professional or respiratory therapist. Do not wear this mask unless the CPAP or Bi-level system is turned on and operating properly. Do not block or try to seal the vent holes.

Explanation of the Warning: CPAP systems are intended to be used with special masks with connectors which have vent holes to allow continuous flow of air out of the mask. When the CPAP machine is turned on and functioning properly, new air from the CPAP machine flushes the exhaled air out through the attached mask exhalation port. However, when the CPAP machine is not operating, enough fresh air will not be provided through the mask, and exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can in some circumstances lead to suffocation. This warning applies to most models of CPAP systems.

3. If oxygen is used with the device, the oxygen flow must be turned off when the device is not operating. Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.

4. At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, mask selection, and the leak rate. This warning applies to most types of CPAP and Bi-level machines.

5. At low CPAP pressures the flow through the vent holes may be inadequate to clear all exhaled gas from the tubing. Some rebreathing may occur.

6. This product may contain chemicals (phthalates) which may cause adverse reactions for the patients who are pregnant or lactational. Consult the healthcare professional before use.

7. Some users may experience skin redness, irritation, or discomfort. If this happens, discontinue use and contact your health care professional.

8. The patient's physician should be contacted if the patient experiences the following symptoms while using the mask or after removing it: unusual chest discomfort, shortness of breath, stomach distension, belching, or severe headache; drying of the eyes, eye pain, or eye infections; blurred vision. (Consult an ophthalmologist if symptoms persist).

9. A minimum of 3cm H₂O (HPa) must be maintained when using this mask.

10. This mask is not recommended for patients who are taking a prescription drug that may cause vomiting.

11. Using a mask may cause tooth, gum, or jaw soreness or aggravate an existing dental condition. Consult your physician or dentist if symptoms occur.

Caution:

1. Do not use if the package is damaged.

2. Read and understand the instructions completely.

3. The mask is supplied as non-sterile. The mask needs to be washed with drinking quality water before first use.

4. Wash patient's face before use.

5. Check the size of the mask and the headgear.

6. The connector of this mask is conical 22mm and complies with the ISO 5356 standard. Check whether the outlet of the oxygen machine matches the mask before

use.

7. Dispose of mask in accordance with local regulations.

Contraindications:

The masks should not be used if the patient is unresponsive or unable to remove the mask by themselves, and it is not recommended for patients who are taking a prescription drug that may cause vomiting.

Side effects:

Some users may experience skin redness, irritation, or discomfort. Some users may experience unusual chest discomfort, shortness of breath, stomach distension, belching, or severe headache; drying of the eyes, eye pain, or eye infections; blurred vision.

Disassembling the Mask:

See section B on the illustrations sheet.

1. Unclip the lower headgear velcro (Fig.B-1).
2. Unclip the upper headgear velcro (Fig.B-2).
3. Press on the both sides of the support arm assembly and move it to the top faceplate, then hold the central part of the support arm assembly and pull it back, so the support arm assembly can be separated from the faceplate.(Fig.B-3).(Non-professional personnel is not recommended to disassembling the support arm assembly in the mask cleaning procedure.)
4. Press the top support arm assembly, remove the bracket from the support arm assembly (Fig.B-4).
5. Remove the forehead pad from the bracket(Fig.B-5).
6. Squeeze and push the upper side tabs on the cushion clip. Pivot away from the mask, and gently pull out(Fig.B-6, Fig.B-7).
7. Separate the cushion from the cushion clip(Fig.B-8)
8. Detach the gasket and remove the assembly elbow from the faceplate (Fig.B-9).
9. Remove the pick off port from the assembly elbow(Fig.B-10).

Cleaning of the CPAP mask

Daily/After Each use:

For the non-sterile mask or reuse mask, it needs a hand wash prior to first use or daily, and the headgear should be hand washed weekly or when needed. The cleaning instruction is as below:

1. Cleaning the pick off port with a soft bristle brush for 1 minute while soaking in the detergent, Alconox (diluted 1%), paying particular attention to crevices and cavities.
Caution: Do not use bleach, alcohol, cleaning solutions containing bleach or alcohol, or cleaning solutions containing conditioners or moisturizers.
2. Rinse thoroughly with drinking quality water(5 liters per mask) three times until clean and air dry out of direct sunlight. Make sure the mask is dry before use. Lay the headgear flat or line dry. Do not place the headgear into the dryer.
3. Inspect the mask. If any parts are damaged or can not be cleaned, replace the mask.

High Level Disinfection of the Mask between Patients

All mask components can be disinfected using validated procedures. The following presents a summary of the validated procedures for disinfection of the system. Refer to the website www.skynector.com for details or contacting Sky Wise Customer Service at +1-800-XXX-XXX.(Please note that,we have applied for the toll-free number and will include it once we have received it.)

The CPAP mask		Sky Wise validated disinfection procedures		Validated number of cycles
		High level thermal disinfection	High level chemical disinfection	
		EN ISO 15883-1 75°C - 30min	Glutaraldehyde 3.4% for 20 minutes	
Nasal mask	NM-03	√	√	15

High level thermal disinfection instruction is as below:

1. Using a certified hot water disinfection system, soak the mask components using a temperature-time combination:

EN ISO 15883-1:

- 75°C for 30minutes

2. Remove the mask components from the hot water disinfection system.
3. Air dry out of direct sunlight.

High level chemical disinfection instruction is as below:

1. Soak the mask components in glutaraldehyde 3.4% for 20 minutes.
2. Rinse thoroughly with drinking quality water(5 liters per mask) three times and air dry out of direct sunlight.

Inspection : Perform a visual inspection of each mask component. If any visible deterioration of a mask component is apparent (cracking, crazing, tears etc), the mask component should be discarded and replaced. Slight discoloration of the silicone components may occur and is acceptable.

Caution: The Mask must be thoroughly cleaned prior to high level disinfection.

Reassembling the Mask

See section C on the illustrations sheet.

Before reassembling the mask, check that all components are clean and dry. Check that the valve is not damaged, distorted or torn, and that none of the other components are broken or cracked. Replace any parts that are damaged.

- 1.Insert the pick off port(Fig.C-1).
- 2.Insert the assembly elbow into the faceplate and fix the gasket(Fig.C-2).
- 3.Place the cushion around the edge of the mask faceplate(Fig.C-3).
- 4.Align the cushion clip with the mask faceplate. Push the cushion clip into the mask faceplate,ensuring that all three clips click into place(Fig.C-4, Fig.C-5).
- 5.Insert the forehead pad into the bracket(Fig.C-6).
- 6.Insert the bracket into the support arm assembly(Fig.C-7).
- 7.Insert the support arm assembly into the top faceplate(Fig.C-8).

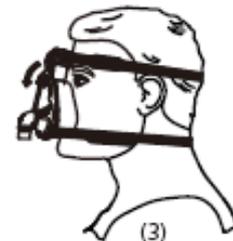
Directions for Use:

1. Make sure the mask is within the expiration date. Tear the package and take out the mask.
2. Cover the mask on the patient's face and fasten with the headgear.

3. Connect the air hose of respiration equipment.

Wearing Methods:

1. Connect the headgear to the mask. Position the mask over your face, and press the mask cushion gently against your face, pull the headgear over your head.
2. Adjust the top and the bottom straps so that the mask is sitting gently on your face.
3. Fasten the mask.



Storage

The packaged masks should be stored in the corrosive gases free, well-ventilated room with $-5^{\circ}\text{C} \sim +50^{\circ}\text{C}$ of the ambient temperature, less than 85% of the relative humidity.

Disposal

The SKynector CPAP Masks does not contain any hazardous substances and may be disposed of with your normal household refuse.

Technical parameters:

Deliverable pressure range :4~30 cmH₂O

Pressure Drop cm H₂O (hPa):

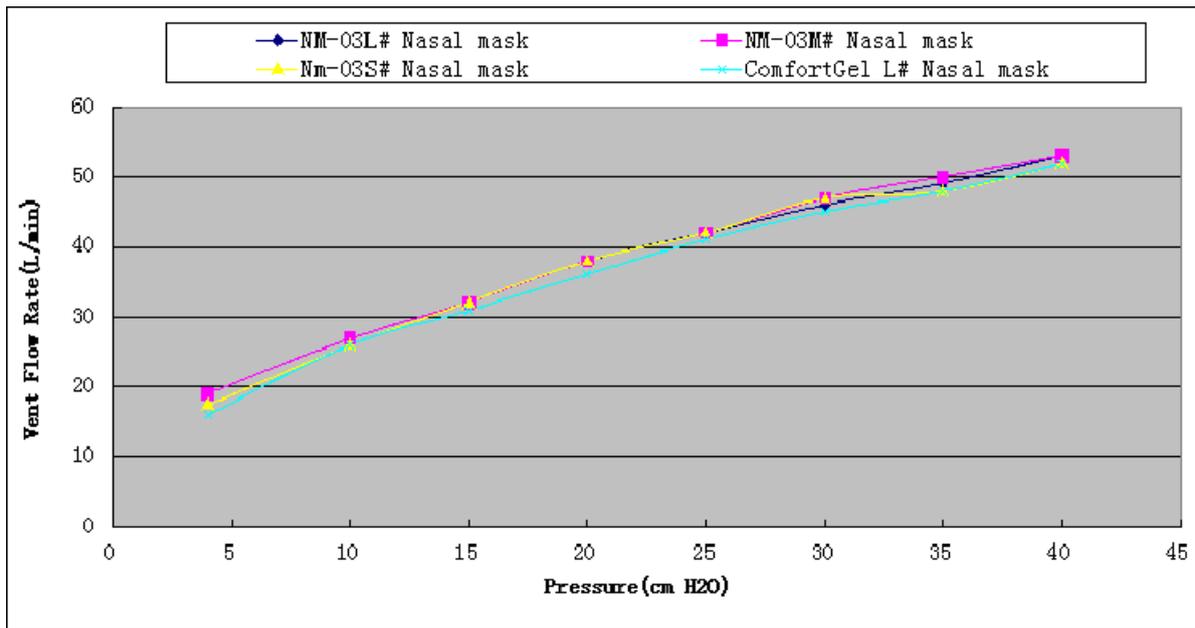
All mask size: 50 SLPM 2.5

100SLPM 8.5

Deadspace Volume

NM-03L 180mL NM-03M 160mL NM-03S 150mL

Pressure-flow curve



Sound

The A-weighted sound power of the mask is 35 dB.

Mask sizes

Size	length(mm)	width(mm)	height(mm)
L	157	106	90
M	155.5	105.5	89
S	155.5	96	90.5

Manufacturer: Sky Wise Medical Instrument (Shenzhen) Co., Ltd.

Address: No 12 South Ping Xi Road Xinsheng Community, Longgang Street, Longgang District, Shenzhen, Guangdong, China

Contact person: Hu hanhan
TEL: +86-755-28491103
FAX: +86-755-28494339
E-Mail: 942526346@qq.com



FM-02 Full-face Mask



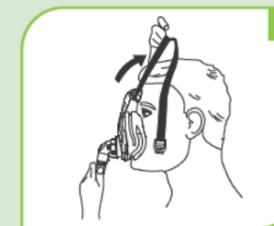
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Full-face Mask FM-02

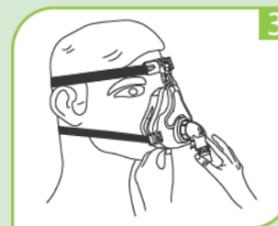
Quick Fitting Guide



Connect top headgear



Position the mask



Connect bottom headgear



Adjust



Adjust



Finish

CPAP Masks (Full-Face Masks)

Style/Size: FM-02 L

FM-02 M

FM-02 S



此处贴对应型号的条码标签



Sky Wise Medical Instrument(ShenZhen)CO.,LTD
Address:No.12 South PingXi Road Xinsheng Community,LongGang Street ,LongGang District ShenZhen

Wellkang Ltd
Suite B, 29 Harley Street
LONDON W1G 9QR, England, United Kingdom



<< www.skynector.com

Made in china



NM-03 Nasal Mask



Nasal Mask NM-03

Quick Fitting Guide



Connect top headgear



Position the mask



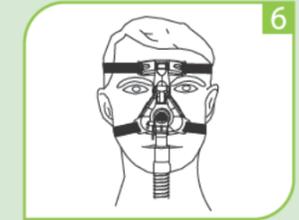
Connect bottom headgear



Adjust



Adjust



Finish

CPAP Masks (Nasal Masks)

Style/Size: NM-03 L

NM-03 M

NM-03 S



此处贴对应型号的条码标签



LOT (See the seal)

Sky Wise Medical Instrument(ShenZhen)CO.,LTD
Address:No.12 South PingXi Road Xinsheng Community,LongGang Street ,LongGang District ShenZhen

Wellkang Ltd
Suite B, 29 Harley Street
LONDON W1G 9QR, England, United Kingdom

(See the seal)



<< www.skynector.com

Made in china

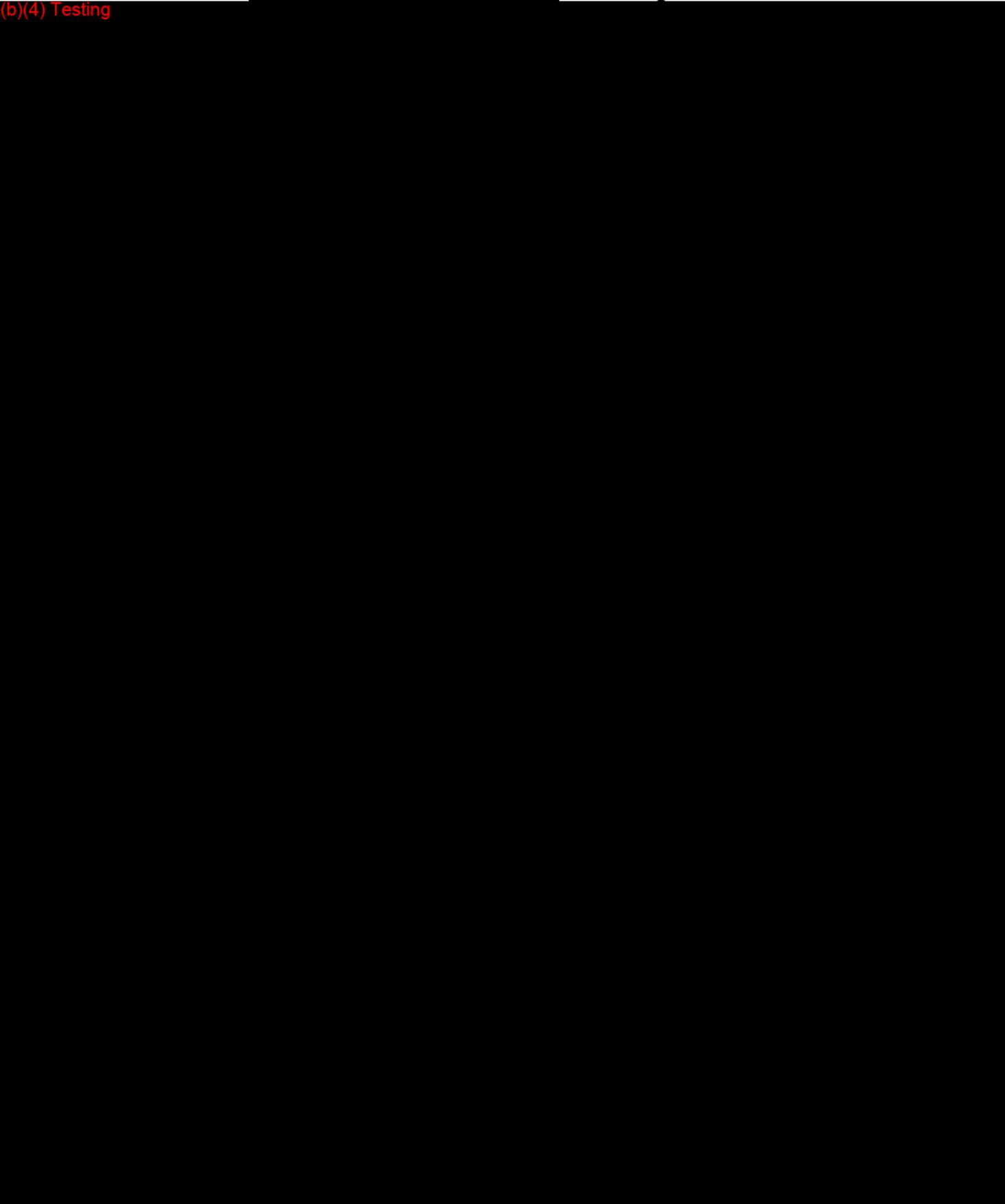


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(b)(4) Testing

Test Report

(b)(4) Testing



(b)(4) Testing

[Display Settings:](#) Abstract[Send to:](#) [J Hosp Infect.](#) 1999 Dec;43(4):293-7.

Residual glutaraldehyde levels in fiberoptic endoscopes: measurement and implications for patient toxicity.

Farina A¹, Fievet MH, Plassart F, Menet MC, Thuillier A.

Author information

¹Groupe Hospitalier Pitié Salpêtrière, Paris, France. agnes.farina@pch.ap-hop-paris.fr

Abstract

Most gastroenterology societies recommend glutaraldehyde for fiberoptic endoscope disinfection. However, glutaraldehyde toxicity has been suspected in patients examined with endoscopes disinfected with this compound. The aim of our study was to determine the residual levels of glutaraldehyde in fiberoptic endoscopes after either manual or automatic disinfection and to evaluate the extent of toxicity. Furthermore, the procedures for disinfection currently performed by the department were compared with the new French guidelines. We used both manual and automatic disinfection procedures and flushed sterile distilled water through the lumens of endoscopes before use. Residual glutaraldehyde levels were determined using liquid chromatography coupled to spectrophotometric detection. In a total of 92 measurements it was found that residual glutaraldehyde levels were higher and more variable after manual disinfection (< 0.2-159.5 mg/L) than after automatic disinfection (< 0.2-6.3 mg/L). We conclude that local procedures for disinfection need to be improved to conform to the new French guidelines. Since thresholds for the toxic dose of glutaraldehyde and international norms for levels of residual glutaraldehyde in equipment have not been defined, additional studies combining accurate measurements in fiberoptic endoscopes and clinical observations of endoscopy patients will be required to draw more definitive conclusions.

Comment in

[Mycobacterium chelonae isolated from rinse water within an endoscope washer-disinfector.](#) [J Hosp Infect. 2000]

PMID: 10658805 [PubMed - indexed for MEDLINE]



MeSH Terms, Substances

LinkOut - more resources

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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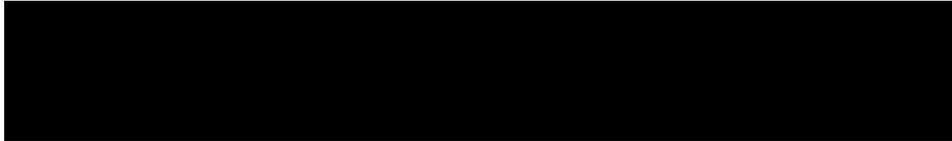


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SKY WISE MEDICAL INSTRUMENT(SHEN ZHEN) CO. , LTD

Statement for Reprocessing Validation

(b)(4)

A large, solid black rectangular redaction box covers the majority of the page content, starting below the section header and extending nearly to the bottom of the page.



Shelf Life

1. Summary

The Skynector CPAP Mask is a prescription device supplied non-sterile. For the Non-sterile mask or reuse mask, it should be cleaned before use. As the CPAP mask is made of plastic, Sky Wise has conducted an (b)(4) test for the shelf life of the CPAP mask, according to ASTM D3045: 1992 Standard Practice for Heat Aging of Plastics without Load. The result shows the CPAP mask's expiration date 2 years is reliable.

2. Cleaning of the CPAP mask

2.1 Daily/After Each use

For the non-sterile mask or reuse mask, it need a hand wash prior to first use or daily, and the headgear should be hand washed weekly or when needed. The cleaning instruction is as below:

- a. Hand wash the mask in warm (30°C) water with a mild liquid dish washing detergent.
Caution: Do not use bleach, alcohol, cleaning solutions containing bleach or alcohol, or cleaning solutions containing conditioners or moisturizers.
- b. Rinse thoroughly with drinking quality water and air dry out of direct sunlight. Make sure the mask is dry before use. Lay the headgear at or line dry. Do not place the headgear into the dryer.
- c. Inspect the mask. If any parts are damaged or can not be cleaned, replace the mask.

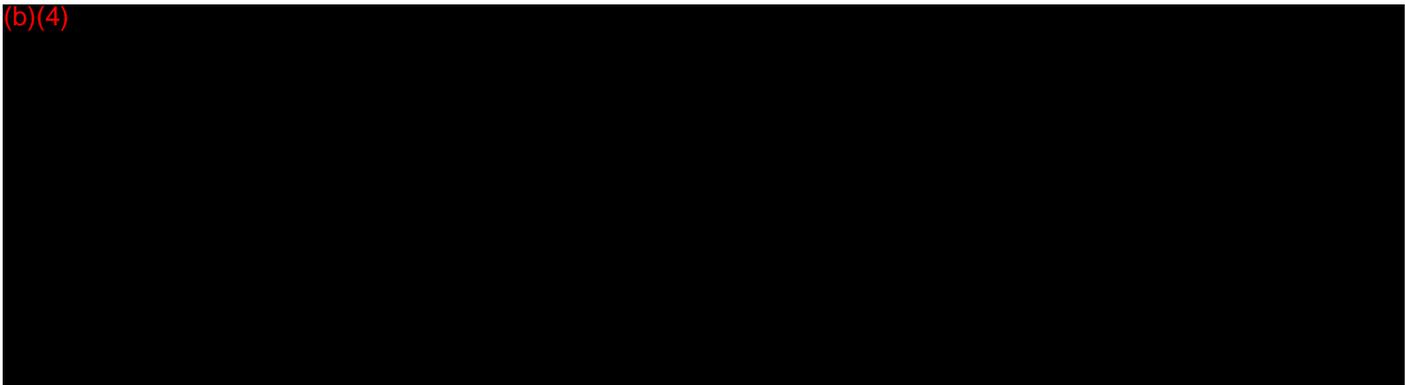
2.2 Reprocessing the Mask between Patients

The mask should be reprocessed when used between patients. The cleaning and disinfection instructions are as below:

The CPAP mask		SkyWise validated disinfection procedures		Validated number of cycles
		High level thermal disinfection	High level chemical disinfection	
		75°C - 30min	Glutaraldehyde 3.4% for 20 minutes	
The full-mask	FM-02	✓	✓	15
The Nasal-mask	NM-03	✓	✓	15

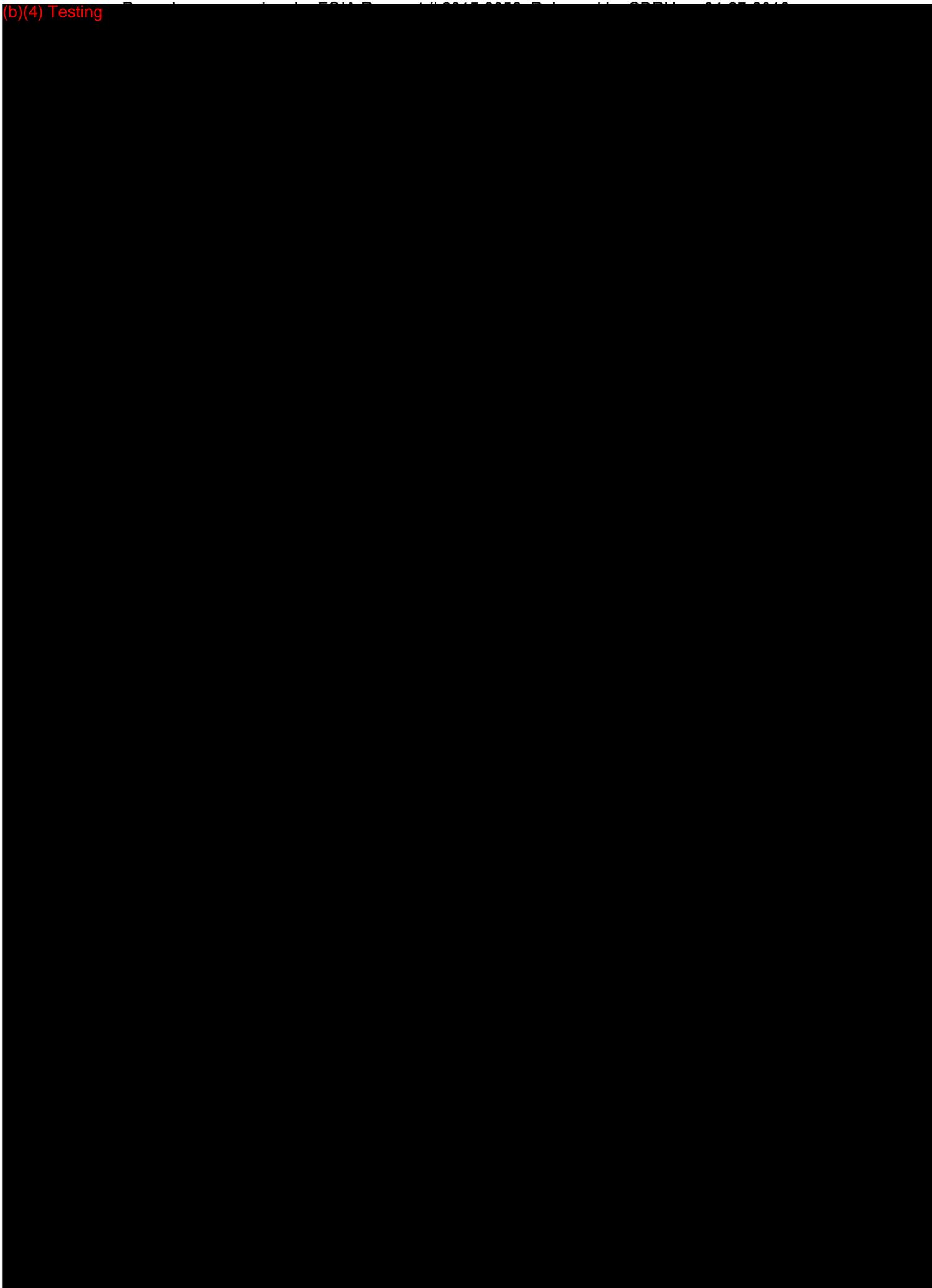
3 (b)(4) test for CPAP Mask

3.1 The basis of the test:



(b)(4) Testing

Product Name: [REDACTED] NDA # [REDACTED] Date: [REDACTED]



SECTION 15 Biocompatibility

There are 6 kinds of patient contacting materials –Silicone Rubber, Polypropylene, Polycarbonate, Polyvinylchloride, nylon and polyester. The 6 kinds of materials (or their combination) respectively constitute the different components, there are not any other ingredients, including plastisizers, additives, cross linkers, reagents, colorants, inks, adhesives, surfactants, detergents, etc., used during the manufacture of the subject device models.

The biocompatibility tests were performed on the 6 kinds of patient contacting materials mentioned above, and the corresponding components are in status of finished product, either assembled into finished mask, or disassembled mechanically from the finished mask, the relevant contacting manner, duration, applicable standards and testing report No. of the tests are as follow:

Table01: Patient contacting materials and corresponding tests (FM-02)

Model	Components	Materials	Contacting manner and duration	Applicable standards	location in this Volume
Full-face Mask FM-02	forehead pad	Silicone Rubber	Skin, permanent	ISO 10993-3,-5,-6, -10,-11	(b)(4)
	cushion	Silicone Rubber	tissue, permanent		
	valve	Silicone Rubber	tissue, permanent		
	bracket	Polycarbonate	Skin, limited	ISO 10993-3,-5,-6, -10,-11	
	swivel	Polycarbonate	tissue, permanent		
	connector	Polycarbonate	tissue, permanent		

Model	Components	Materials	Contacting manner and duration	Applicable standards	location in this Volume
	vent	Polycarbonate	tissue, permanent		(b)(4) Testing
	elbow	Polycarbonate	tissue, permanent		
	pick off port	Polyvinylchloride	Skin, permanent	ISO 10993-3,-5,-6, -10,-11	
	faceplate	Polypropylene	Skin, limited	ISO 10993-5, -10	
headgear	nylon, polyester	Skin, permanent	ISO 10993-5, -		

Model	Components	Materials	Contacting manner and duration	Applicable standards	location in this Volume
				10	(b)(4) Testing

Table02: Patient contacting materials and corresponding tests (NM-03)

Model	Components	Materials	Contacting manner and duration	Applicable standards	location in this Volume
Nasal mask NM-03	forehead pad	Silicone Rubber	Skin, permanent	ISO 10993-3,-5,-6, -10,-11	(b)(4)
	cushion	Silicone Rubber	tissue, permanent		
	faceplate	Polycarbonate	Skin, limited		
	bracket	Polycarbonate	Skin, limited		
	support arm assembly	Polycarbonate	Skin, limited		
	cushion clip	Polycarbonate	Skin, limited		
	gasket	Polycarbonate	tissue, permanent		
	swivel	Polycarbonate	tissue, permanent		
	elbow	Polycarbonate	tissue, permanent		
	pick off port	Polyvinylchloride	Skin, permanent		

Model	Components	Materials	Contacting manner and duration	Applicable standards	location in this Volume
				-6, -10,-11	(b)(4)
	headgear	nylon, polyester	Skin, permanent	ISO 10993-5, -10	(b)(4)

Note (b)(4)

(b)(4)

Sky Wise Medical Instrument (Shenzhen) Co., Ltd.

(b)(4) Third Party

Product: Skynector CPAP Mask

Version: (b)

(4)

SECTION 16 Software

(not applicable)

This section is not applicable, for the device is a non-active one, does not contain any software and/or firmware.

Sky Wise Medical Instrument (Shenzhen) Co., Ltd.

(b)(4) Third Party EMC and Electric Safety

Product: Skynector CPAP Mask

Version: (b)(4)

bb

SECTION 17 EMC and Electric Safety

(Not applicable)

This section is not applicable, for the device is a non-active one.



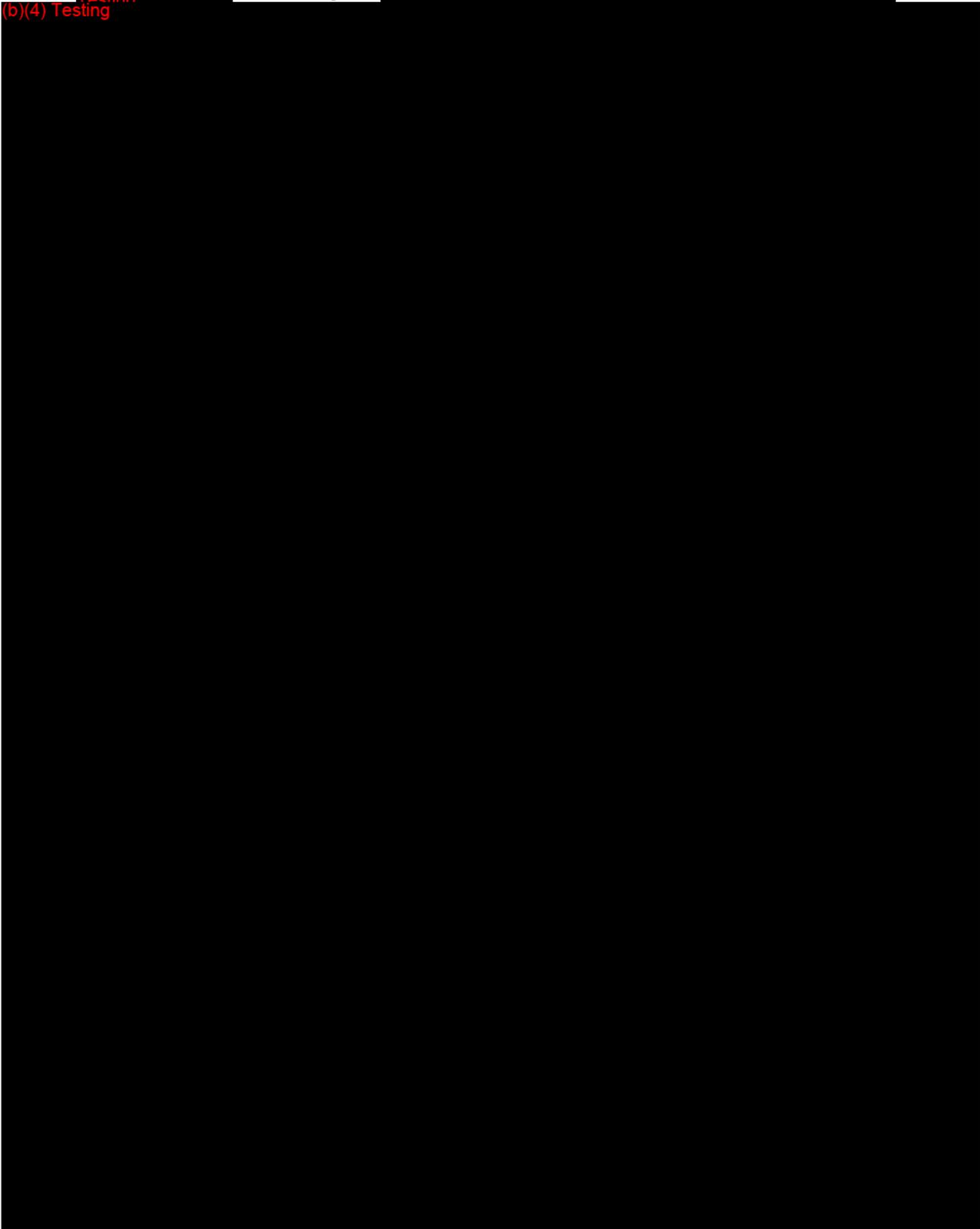
慧天医疗器械（深圳）有限公司
SKY WISE MEDICAL INSTRUMENT(SHEN ZHEN) CO. , LTD

(b)(4) Third Party
Testing

Test Report

(b)(4) Third Party Testing

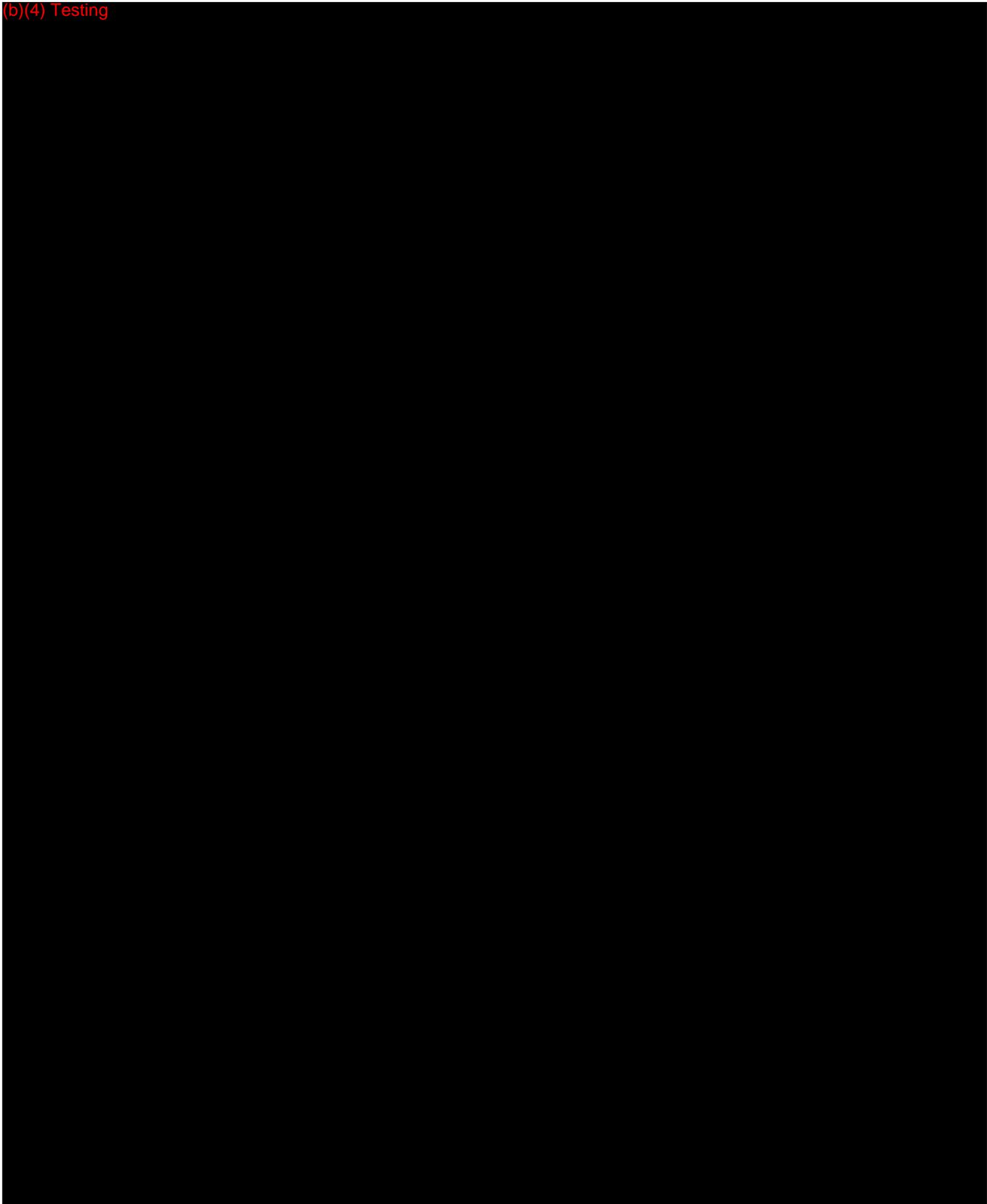
(b)(4) Testing





(b)(4) Testing test report for the Skynector CPAP Mask

(b)(4) Testing





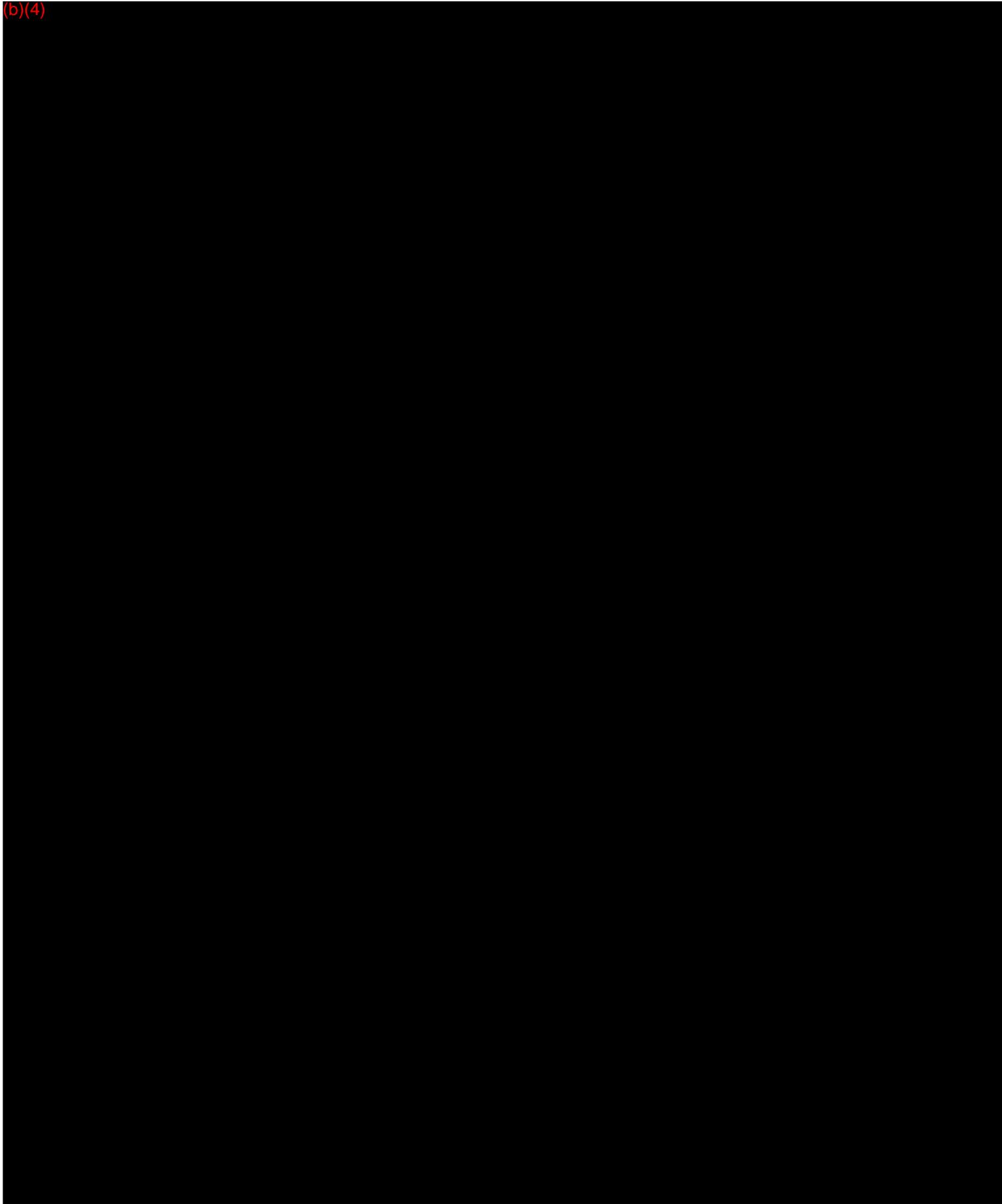
Skynector

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(b)(4) Manufacturing
Information

test report for the Skynector CPAP Mask

(b)(4)



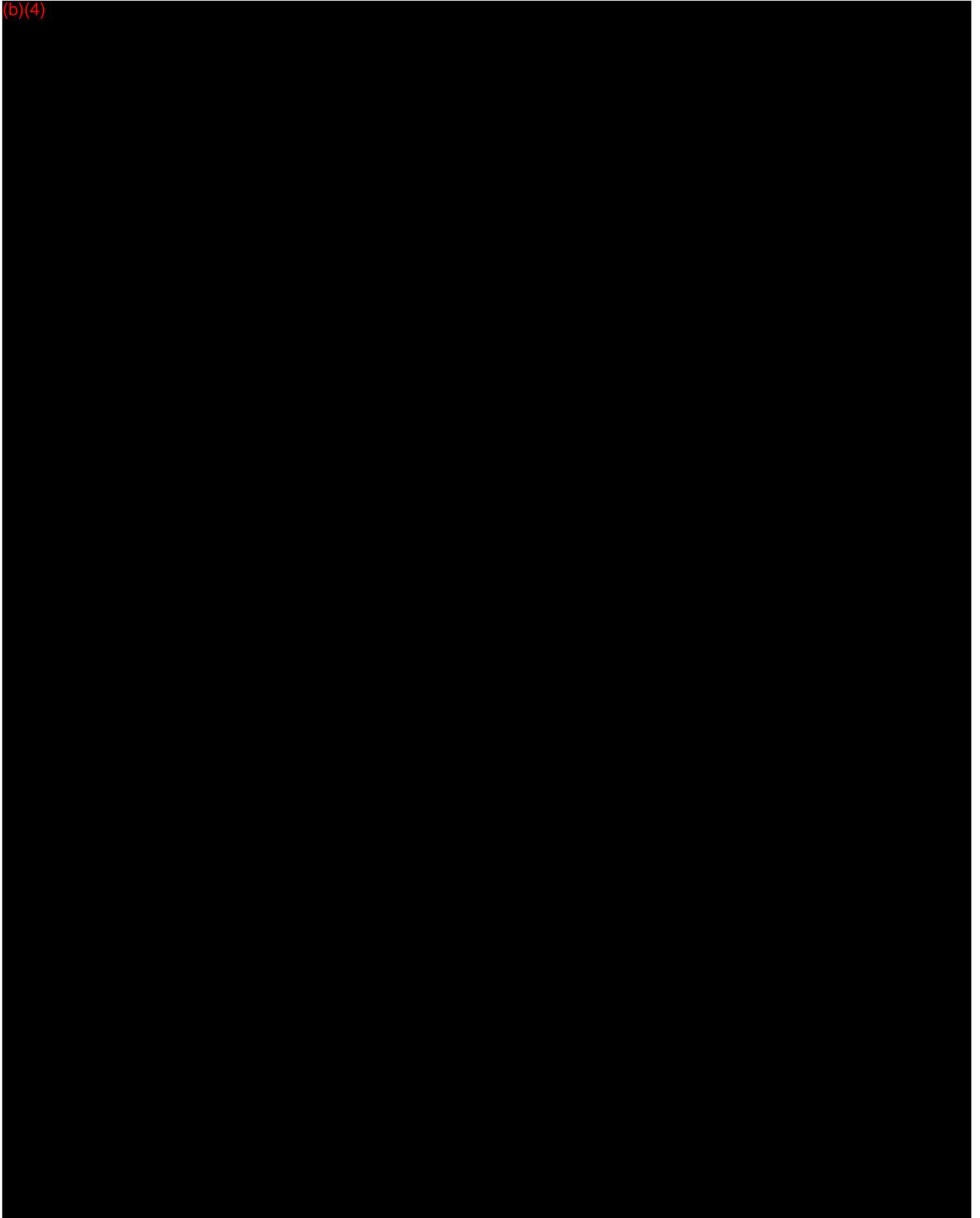


Skynector

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SKY WISE MEDICAL INSTRUMENT(SHEN ZHEN) CO. , LTD

(b)(4)

test report for the Skynector CPAP Mask



(b)(4)

Sky Wise Medical Instrument (Shenzhen) Co., Ltd.	(b)(4)	Animal testing
Product: Skynector CPAP Mask		Version (b)(4)

SECTION 19 Performance Testing – Animal (not applicable)

This section is not applicable, for the lineament of animal is completely different from the human's, it is unnecessary to do animal testing.

Sky Wise Medical Instrument (Shenzhen) Co., Ltd.

(b)(4) _Clinical

Product: Skynector CPAP Mask

Version (b)

(4)

SECTION 20 Performance Testing – Clinical (not applicable)

This section is not applicable, for the use of vented masks with (b)(4) (b)(4) is proven technology and is well accepted by the medical community. Clinical data was not relied upon to demonstrate Substantial Equivalence to predicate devices. Bench testing alone is sufficient.

Records processed under FOIA Request # 2015-0052, Released by CDRH on 04-27-2016



Food and Drug Administration

**Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with
Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))**

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER Sky Wise Medical Instrument (Shenzhen) Co., Ltd.	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES 02/28/2014
3. ADDRESS (Number, Street, State, and ZIP Code) No. 12 South PingXi Road, Xinsheng Community, Longgang Street Longgang District, Shenzhen, Guangdong, China.	4. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) +86-755-28491103 (Fax) +86-755-28494339

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

Common Name: full face mask, nasal mask. Trade Name: Skynector CPAP Mask

Models: FM-02, NM-03 Classification: ventilator, non-continuous (respirator)

Product Code: BZD

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

IND NDA ANDA BLA PMA HDE 510(k) PDP Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned)

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation)

A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary)

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) Hu hanhan (Title) Management Representative	
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12) No. 12 South PingXi Road, Xinsheng Community, Longgang Street Longgang District, Shenzhen, Guangdong, China.	14. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) +86-755-28491103 (Fax) +86-755-28494339	15. DATE OF CERTIFICATION 02/28/2014

Instructions for Completion of Form FDA 3674

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date** - This is the date of the application/submission which the certification accompanies.
3. & 4. - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field.
9. **Certification** - This section contains three different check-off boxes.
Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.
Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply to any of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply at the time of submission to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as NCT will be added automatically before number. Include any and all NCT numbers assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11.** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. & 14. - Provide the full address, telephone and fax number of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the applicable address below.

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
Form No. FDA 3674
5901-B Ammendale Road
Beltsville, MD 20705-1266

Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville, MD 20852-1448

Food and Drug Administration
Center for Devices and Radiological Health
Program Operations Staff (HFZ-403)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number.

Department of Health and Human Services
 Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
 (To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #1-62

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
 If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Part1	Anaesthetic and respiratory equipment -- Conical connectors -- Part 1: Cones a	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION
ALL APPLICABLE CLAUSE ARE MEETED

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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Department of Health and Human Services
 Food and Drug Administration
 Office of Chief Information Officer
 1350 Piccard Drive, Room 400
 Rockville, MD 20850

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Food and Drug Administration
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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

AAMI/ANSI/ISO10993-5:2009, Biological evaluation of medical devices-Part 5:Test for In Vitro Cytotoxicity.(Biocompatibility)

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #2-153

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
AAMI/ANSI/ISO10993-5:2009, Biological evaluation of medical devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Part 5	Test for In Vitro Cytotoxicity. (Biocompatibility)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION
ALL APPLICABLE CLAUSE ARE MEETED

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.
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Paperwork Reduction Act Statement

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Food and Drug Administration
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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. (Biocompatibility)

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #2-174

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 10993-10:2010, Biological evaluation of medical devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Part 10	Tests for irritation and skin sensitization. (Biocompatibility)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [♦]

DESCRIPTION
ALL APPLICABLE CLAUSE ARE MEETED

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [♦]

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [♦]

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Paperwork Reduction Act Statement

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Food and Drug Administration
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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #2-120

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Part 6	Biological evaluation of medical devices -- Part 6: Tests for local effects after i	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION
ALL APPLICABLE CLAUSE ARE MEETED

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Paperwork Reduction Act Statement

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Department of Health and Human Services
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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

Biological evaluation of medical devices -- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #2-175

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
 If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Part 3	Biological evaluation of medical devices -- Part 3: Tests for genotoxicity, carci	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION
ALL APPLICABLE CLAUSE ARE MEETED

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

Sleep apnoea breathing therapy - Part 2: Masks and application accessories

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 1-92

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Part 2	Sleep apnoea breathing therapy - Part 2: Masks and application accessories	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION
ALL APPLICABLE CLAUSE ARE MEETED

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Department of Health and Human Services
 Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
 (To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

Standard Practice for Heat Aging of Plastics Without Load

Please answer the following questions

Yes No

Is this standard recognized by FDA ²? Yes No

FDA Recognition number ³ # _____

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? Yes No

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? Yes No
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? Yes No

Does this standard include acceptance criteria? Yes No
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? Yes No
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?..... Yes No
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵? Yes No

Were deviations or adaptations made beyond what is specified in the FDA SIS?..... Yes No
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? Yes No
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?..... Yes No
 If yes, was the guidance document followed in preparation of this 510k? Yes No

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
	Standard Practice for Heat Aging of Plastics Without Load	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION
ALL APPLICABLE CLAUSE ARE MEETED

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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Rockville, MD 20850

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Sky Wise Medical Instrument (Shenzhen) Co., Ltd.

(b) (4)

Risk Management

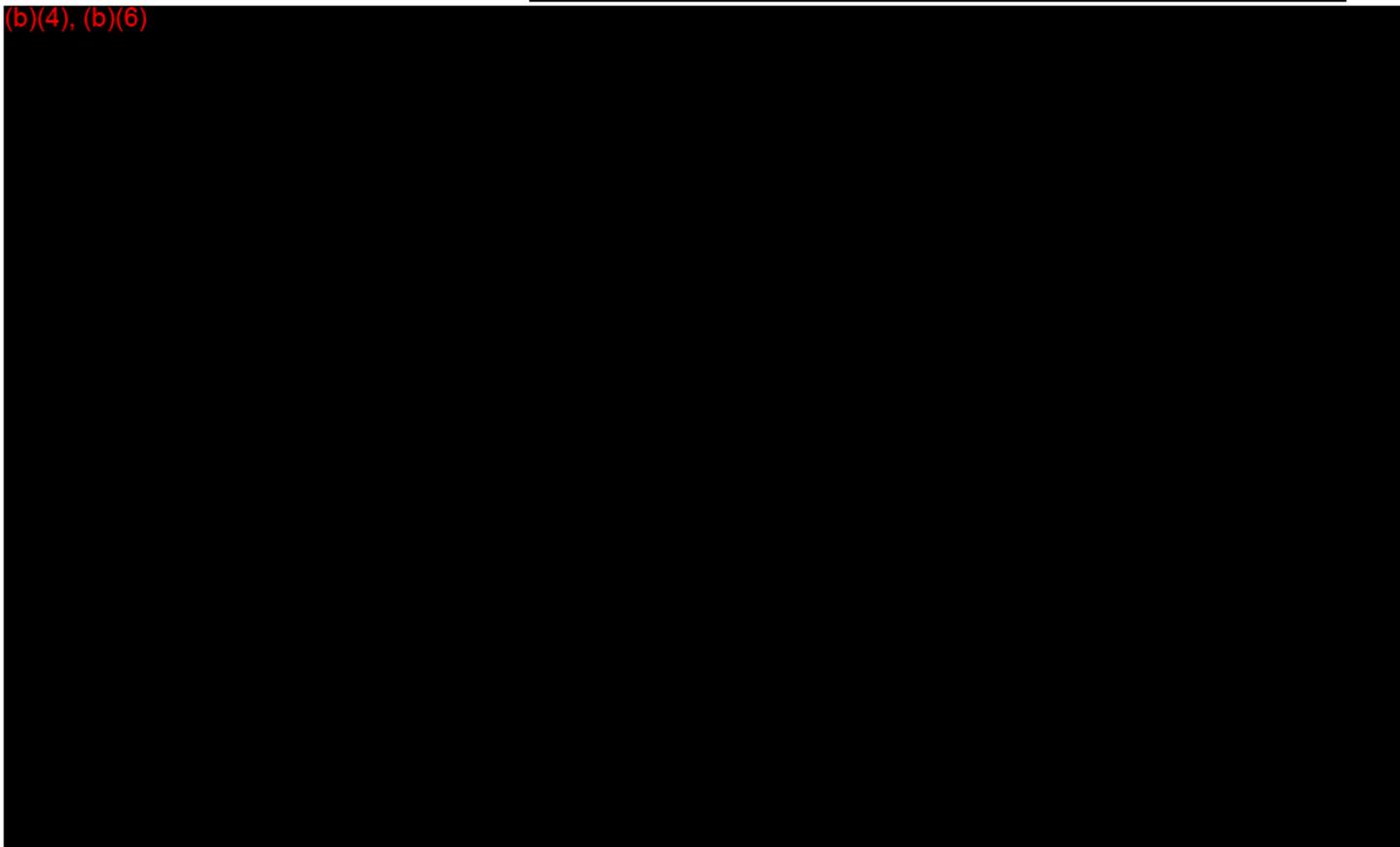
Product: Skynector CPAP Mask

Version (b) (4)

SECTION 22: Risk Management Report

Product Name: Skynector CPAP Mask

(b)(4), (b)(6)



FDA/CDRH DMC
MAY 13 2015

Sky Wise Medical Instrument (Shenzhen) Co., Ltd.
Product: Skynector CPAP Mask

(b)(4)
Cover Letter
Version: (b)(4)

Received

K150685/S002
K150685 S001

Cover Letter for 510(k) S001

Dear FDA reviewer:

Thank you for reviewing 510(k) submission, K150685, and I am grateful to you for making the comments on it. The supplementary information requested had been prepared and sent to you.

The eCopy of the additional information had been sent along with the hard copy, I state here:

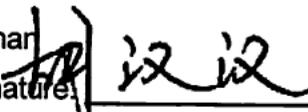
eCopy Statement

Per the instructions accessed at <http://www.fda.gov/cdrh/elecsb.html>, an electronic copy is being provided with this submission and it is an exact duplicate of the original paper submission.

Please let me know if you have any questions or concerns, please feel free to contract me with E-mail or Fax. Thanks!

Sincerely Yours,

Management Representative: Hu hanhan

Signature: 

Date: 2015, May, 04.



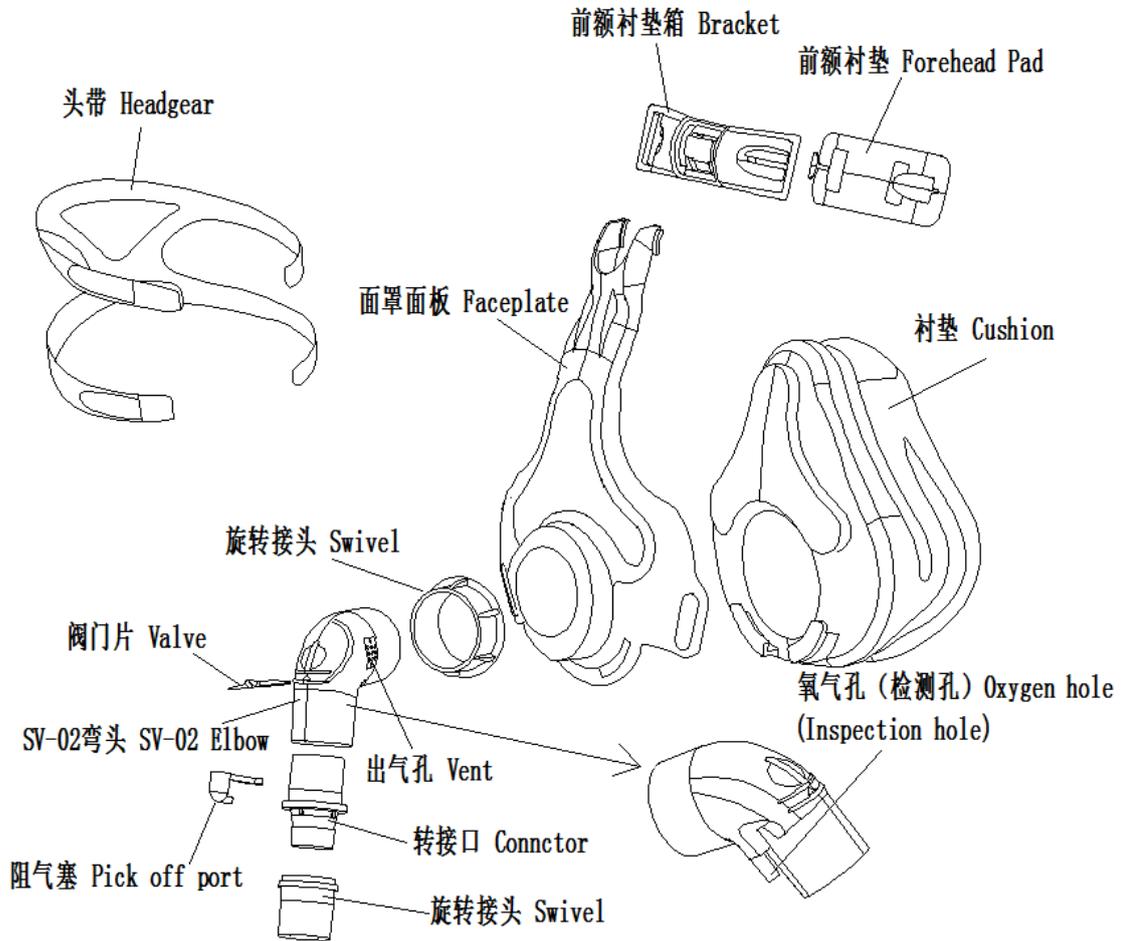
Instruction For Use

FM-02 Series CPAP Full-Face Mask

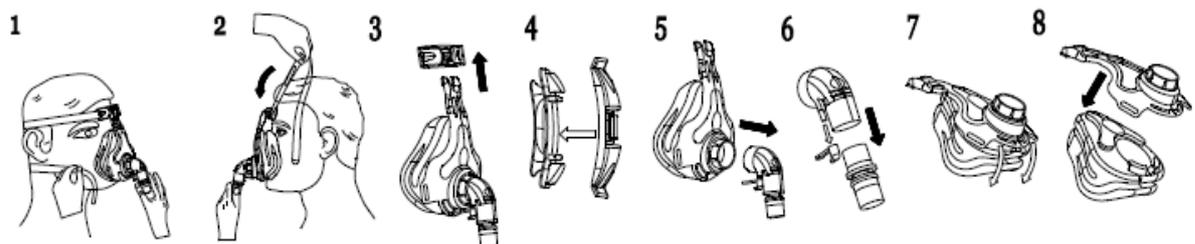
User Guide

English

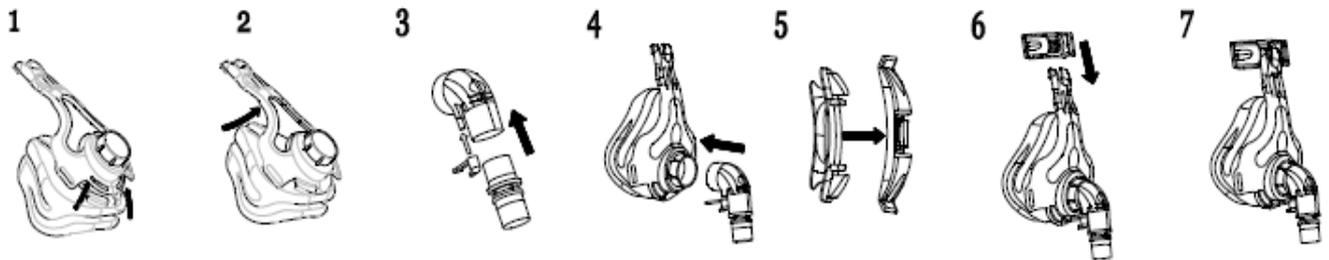
A Structure Description



B Disassembling for cleaning



C Reassembling the mask



Skynector CPAP

FM-02 Full-Face Mask

Thank you for choosing Skynector CPAP Full-Face Mask.

The Skynector CPAP Full-Face Mask is a system that covers your nose and mouth. This means that you can receive effective therapy even if you breathe through your mouth. The mask incorporates vent holes and a built-in valve so that you can continue to breathe fresh air if the airflow to your mask is impeded for any reason.

Intended Use/Indications for Use

The Skynector CPAP Mask channels airflow non-invasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system.

The Skynector CPAP Mask is to be used by adult patients (>66lb / >30kg) for whom positive airway pressure has been prescribed.

The Skynector CPAP Mask is intended for single patient re-use in the home environment and/or multi-patient reuse in the hospital /institutional environment.

Before Using the Mask

WARNINGS

1. This mask is not suitable for providing life support ventilation.
2. This mask is designed for use with CPAP or Bi-level systems recommended by your health care professional or respiratory therapist. Do not wear this mask unless the

CPAP or Bi-level system is turned on and operating properly. Do not block or try to seal the vent holes.

Explanation of the Warning: CPAP systems are intended to be used with special masks with connectors which have vent holes to allow continuous flow of air out of the mask. When the CPAP machine is turned on and functioning properly, new air from the CPAP machine flushes the exhaled air out through the attached mask exhalation port. However, when the CPAP machine is not operating, enough fresh air will not be provided through the mask, and exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can in some circumstances lead to suffocation. This warning applies to most models of CPAP systems.

3. If oxygen is used with the device, the oxygen flow must be turned off when the device is not operating. Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.
4. At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, mask selection, and the leak rate. This warning applies to most types of CPAP and Bi-level machines.
5. At low CPAP pressures the flow through the vent holes may be inadequate to clear all exhaled gas from the tubing. Some rebreathing may occur.
6. This product may contain chemicals (phthalates) which may cause adverse reactions for the patients who are pregnant or lactational. Consult the health care professional before use.
7. Some users may experience skin redness, irritation, or discomfort. If this happens, discontinue use and contact your health care professional.
8. The patient's physician should be contacted if the patient experiences the following symptoms while using the mask or after removing it: Unusual chest discomfort, shortness of breath, stomach distension, belching, or severe headache; drying of the eyes, eye pain, or eye infections; blurred vision. (Consult an ophthalmologist if symptoms persist).
9. A minimum of 3cm H₂O (HPa) must be maintained when using this mask.
10. This mask is not recommended for patients who are taking a prescription drug that may cause vomiting.
11. Using a mask may cause tooth, gum, or jaw soreness or aggravate an existing dental condition. Consult your physician or dentist if symptoms occur.

Caution:

1. Do not use if the package is damaged.
2. Read and understand the instructions completely.
3. The mask is supplied as non-sterile. The mask needs to be washed with drinking quality water before first use.
4. Wash patient's face before use.

5. Check the size of the mask and the headgear.
6. The connector of this mask is conical 22mm and complies with the ISO 5356 standard. Check whether the outlet of the oxygen machine matches the mask before use.
7. Dispose of mask in accordance with local regulations.

Contraindications:

The masks should not be used if the patient is unresponsive or unable to remove the mask by themselves, and it is not recommended for patients who are taking a prescription drug that may cause vomiting.

Side effects:

Some users may experience skin redness, irritation, or discomfort. Some users may experience unusual chest discomfort, shortness of breath, stomach distension, belching, or severe headache; drying of the eyes, eye pain, or eye infections; blurred vision.

Disassembling the Mask:

See section B on the illustrations sheet.

1. Unclip the lower headgear velcro (Fig.B-1).
2. Unclip the upper headgear velcro (Fig.B-2).
3. Press the top faceplate, remove the bracket from the faceplate(Fig.B-3).
4. Remove the forehead pad from the bracket(Fig.B-4).
5. Remove the connector from the mask faceplate(Fig.B-5).It's easier to pivot the bottom of the connector away from the mask faceplate than to pull the connector straight off.
6. Detach the swivel from the elbow(Fig.B-6).
7. Squeeze and push the upper side tabs on the cushion out of the faceplate(Fig.B-7). Pivot away from the faceplate, and gently pull out.
8. Separate the cushion from the faceplate. (Fig.B-8).

Cleaning of the CPAP mask

Daily/After Each use:

For the non-sterile mask or reuse mask, it need a hand wash prior to first use or daily, and the headgear should be hand washed weekly or when needed. The cleaning instruction is as below:

1. Cleaning the pick off port with a soft bristle brush for 1 minute while soaking in the detergent, Alconox (diluted 1%), paying particular attention to crevices and cavities. Caution: Do not use bleach, alcohol, cleaning solutions containing bleach or alcohol, or cleaning solutions containing conditioners or moisturizers.
2. Rinse thoroughly with drinking quality water(5 liters per mask) three times until clean and air dry out of direct sunlight. Make sure the mask is dry before use. Lay the headgear flat or line dry. Do not place the headgear into the dryer.
3. Inspect the mask. If any parts are damaged or can not be cleaned, replace the mask.

High Level Disinfection of the Mask between Patients

All mask components can be disinfected using validated procedures. The following presents a summary of the validated procedures for disinfection of the system. Refer to the website www.skynector.com for details or contacting Skywise Customer Service at +86 (0)755 28494331.

The CPAP mask		Sky Wise validated disinfection procedures		Validated number of cycles
		High level thermal disinfection	High level chemical disinfection	
		EN ISO 15883-1 75°C - 30min	Glutaraldehyde 3.4% for 20 minutes	
Full-face	FM-02	✓	✓	15

High level thermal disinfection instruction is as below:

1. Using a certified hot water disinfection system, soak the mask components using a temperature-time combination:

EN ISO 15883-1:

- 75°C for 30minutes
2. Remove the mask components from the hot water disinfection system.
 3. Air dry out of direct sunlight.

High level chemical disinfection instruction is as below:

1. Soak the mask components in glutaraldehyde 3.4% for 20 minutes.
2. Rinse thoroughly with drinking quality water(5 liters per mask) three times and air dry out of direct sunlight.

Inspection : Perform a visual inspection of each mask component. If any visible deterioration of a mask component is apparent (cracking, crazing, tears etc), the mask component should be discarded and replaced. Slight discolouration of the silicone components may occur and is acceptable.

Caution: The Mask must be thoroughly cleaned prior to high level disinfection.

Reassembling the Mask

See section C on the illustrations sheet.

Before reassembling the mask, check that all components are clean and dry. Check that the valve is not damaged, distorted or torn, and that none of the other components are broken or cracked. Replace any parts that are damaged.

1. Insert the upper side tabs on the lower cushion into the faceplate(Fig.C-1).
Insert the upper cushion into the faceplate(Fig.C-2).Ensure that the cushion is not twisted or distorted.
2. Insert the swivel into the end of the elbow(Fig.C-3).
3. Insert the assembled connector into the mask faceplate(Fig.C-4).
4. Insert the forehead pad into the bracket(Fig.C-5).
5. Press the top faceplate, insert the bracket into the faceplate(Fig.C-6).

Directions for Use:

1. Make sure the mask is within the expiration date. Tear the package and take out the mask.
2. Cover the mask on the patient's face and fasten with the headgear.
3. Connect the oxygen hose to the oxygen supply.

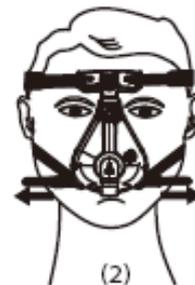
Caution: Federal law restricts this device to sale by or on the order of a physician.

Wearing Methods:

1. Connect the headgear to the mask. Position the mask over your face, and press the mask cushion gently against your face, pull the headgear over your head.



2. Adjust the top and the bottom straps so that the mask is sitting gently on your face.



3. Fasten the mask.



Technical parameters:

Deliverable pressure range :4~20 cmH₂O

Pressure Drop cm H₂O (hPa):

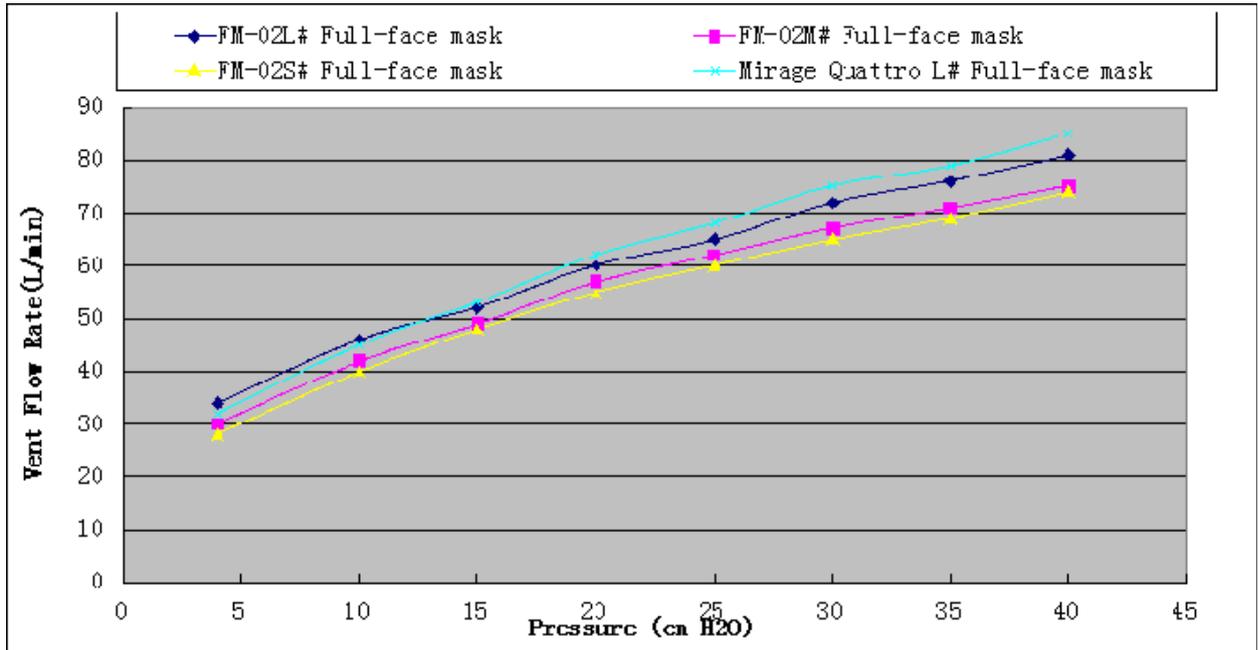
All mask size: 50 SLPM 0.5

100 SLPM 1.5

Deadspace Volume

FM-02L: 358mL; FM-02M: 311mL; FM-02S: 280mL

Pressure-flow curve



Open/close pressure for anti-asphyxia valve (cmH₂O):

Open pressure:2.0 close pressure:1.5

Storage

The packaged masks should be stored in the corrosive gases free, well- ventilated room with -5°C~+50°C of the ambient temperature, less than 85% of the relative humidity.

Mask sizes

Size	length(mm)	width(mm)	height(mm)
L	215	120.5	130
M	215	115.5	130
S	215	115.5	126

Manufacturer: Sky Wise Medical Instrument (Shenzhen) Co., Ltd.

Address: No 12 South Ping Xi Road Xinsheng Community, Longgang Street, Longgang District, Shenzhen, Guangdnog, China

Contact person: Hu hanhan
 TEL: +86-755-28491103
 FAX: +86-755-28494339
 E-Mail: 942526346@qq.com



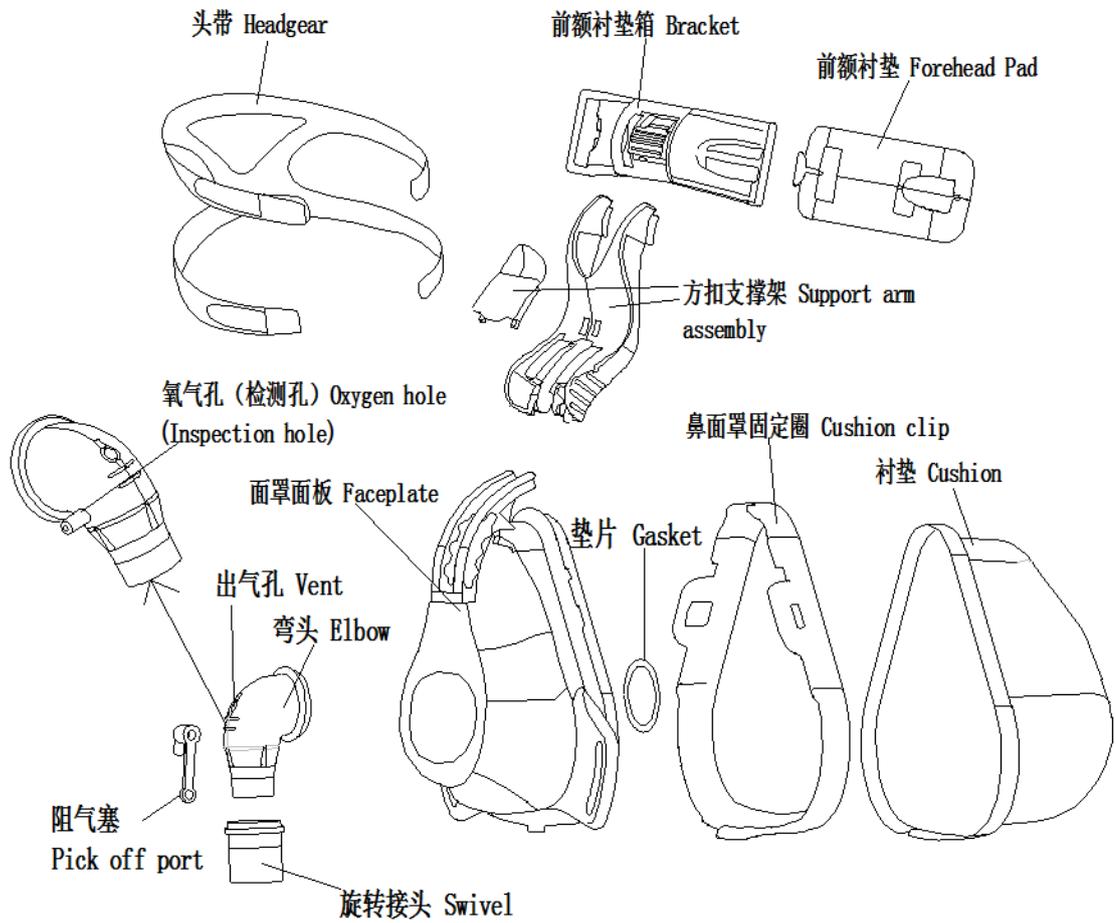
Instruction For Use

NM-03 Series CPAP Nasal Mask

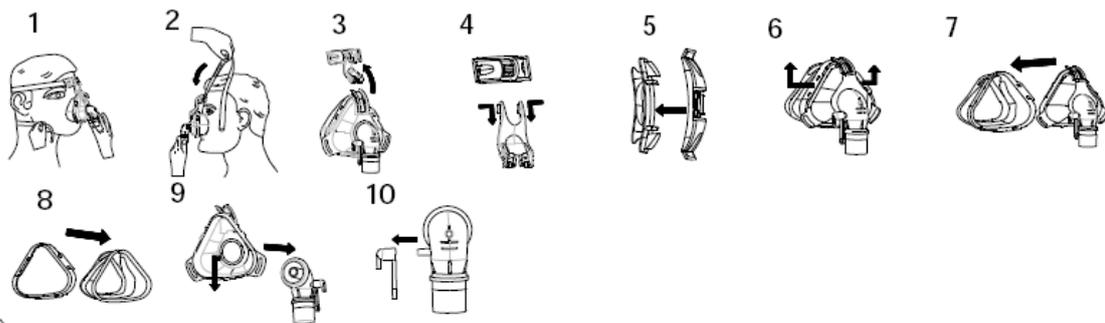
User Guide

English

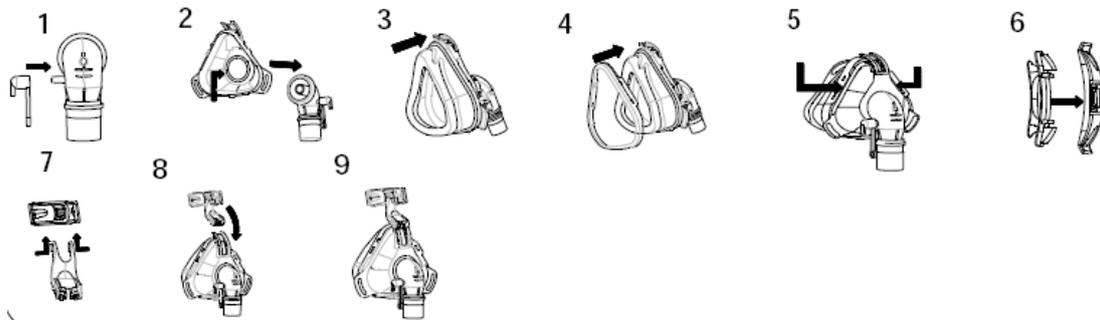
A Structure Description



B Disassembling for cleaning



C Reassembling the mask



Skynector CPAP

NM-03 Nasal Mask

Thank you for choosing Skynector CPAP Nasal Mask.

The Skynector CPAP Nasal Mask is a system that covers your nose only. The mask incorporates vent holes to reduce carbon dioxide rebreathing.

Intended Use/Indications for Use

The Skynector CPAP Mask channels airflow non-invasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system.

The Skynector CPAP Mask is to be used by adult patients (>66lb / >30kg) for whom positive airway pressure has been prescribed.

The Skynector CPAP Mask is intended for single patient re-use in the home environment and/or multi-patient reuse in the hospital /institutional environment.

Before Using the Mask



WARNINGS

1. This mask is not suitable for providing life support ventilation.
2. This mask is designed for use with CPAP or Bi-level systems recommended by your health care professional or respiratory therapist. Do not wear this mask unless the CPAP or Bi-level system is turned on and operating properly. Do not block or try to seal the vent holes.

Explanation of the Warning: CPAP systems are intended to be used with special masks with connectors which have vent holes to allow continuous flow of air out of the mask. When the CPAP machine is turned on and functioning properly, new air from the CPAP machine flushes the exhaled air out through the attached mask exhalation port. However, when the CPAP machine is not operating, enough fresh air will not be provided through the mask, and exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can in some circumstances lead to suffocation. This warning applies to most models of CPAP systems.

3. If oxygen is used with the device, the oxygen flow must be turned off when the device is not operating. Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.

4. At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, mask selection, and the leak rate. This warning applies to most types of CPAP and Bi-level machines.

5. At low CPAP pressures the flow through the vent holes may be inadequate to clear all exhaled gas from the tubing. Some rebreathing may occur.

6. This product may contain chemicals (phthalates) which may cause adverse reactions for the patients who are pregnant or lactational. Consult the healthcare professional before use.

7. Some users may experience skin redness, irritation, or discomfort. If this happens, discontinue use and contact your health care professional.

8. The patient's physician should be contacted if the patient experiences the following symptoms while using the mask or after removing it: unusual chest discomfort, shortness of breath, stomach distension, belching, or severe headache; drying of the eyes, eye pain, or eye infections; blurred vision. (Consult an ophthalmologist if symptoms persist).

9. A minimum of 3cm H₂O (HPa) must be maintained when using this mask.

10. This mask is not recommended for patients who are taking a prescription drug that may cause vomiting.

11. Using a mask may cause tooth, gum, or jaw soreness or aggravate an existing dental condition. Consult your physician or dentist if symptoms occur.

Caution:

1. Do not use if the package is damaged.

2. Read and understand the instructions completely.

3. The mask is supplied as non-sterile. The mask needs to be washed with drinking quality water before first use.

4. Wash patient's face before use.

5. Check the size of the mask and the headgear.

6. The connector of this mask is conical 22mm and complies with the ISO 5356 standard. Check whether the outlet of the oxygen machine matches the mask before

use.

7. Dispose of mask in accordance with local regulations.

Contraindications:

The masks should not be used if the patient is unresponsive or unable to remove the mask by themselves, and it is not recommended for patients who are taking a prescription drug that may cause vomiting.

Side effects:

Some users may experience skin redness, irritation, or discomfort. Some users may experience unusual chest discomfort, shortness of breath, stomach distension, belching, or severe headache; drying of the eyes, eye pain, or eye infections; blurred vision.

Disassembling the Mask:

See section B on the illustrations sheet.

1. Unclip the lower headgear velcro (Fig.B-1).
2. Unclip the upper headgear velcro (Fig.B-2).
3. Press on the both sides of the support arm assembly and move it to the top faceplate, then hold the central part of the support arm assembly and pull it back, so the support arm assembly can be separated from the faceplate.(Fig.B-3).(Non-professional personnel is not recommended to disassembling the support arm assembly in the mask cleaning procedure.)
4. Press the top support arm assembly, remove the bracket from the support arm assembly (Fig.B-4).
5. Remove the forehead pad from the bracket(Fig.B-5).
6. Squeeze and push the upper side tabs on the cushion clip. Pivot away from the mask, and gently pull out(Fig.B-6, Fig.B-7).
7. Separate the cushion from the cushion clip(Fig.B-8)
8. Detach the gasket and remove the assembly elbow from the faceplate (Fig.B-9).
9. Remove the pick off port from the assembly elbow(Fig.B-10).

Cleaning of the CPAP mask

Daily/After Each use:

For the non-sterile mask or reuse mask, it needs a hand wash prior to first use or daily, and the headgear should be hand washed weekly or when needed. The cleaning instruction is as below:

1. Cleaning the pick off port with a soft bristle brush for 1 minute while soaking in the detergent, Alconox (diluted 1%), paying particular attention to crevices and cavities.
Caution: Do not use bleach, alcohol, cleaning solutions containing bleach or alcohol, or cleaning solutions containing conditioners or moisturizers.
2. Rinse thoroughly with drinking quality water(5 liters per mask) three times until clean and air dry out of direct sunlight. Make sure the mask is dry before use. Lay the headgear flat or line dry. Do not place the headgear into the dryer.
3. Inspect the mask. If any parts are damaged or can not be cleaned, replace the mask.

High Level Disinfection of the Mask between Patients

All mask components can be disinfected using validated procedures. The following presents a summary of the validated procedures for disinfection of the system. Refer to the website www.skynector.com for details or contacting Sky Wise Customer Service at +1-800-XXX-XXX.(Please note that,we have applied for the toll-free number and will include it once we have received it.)

The CPAP mask		Sky Wise validated disinfection procedures		Validated number of cycles
		High level thermal disinfection	High level chemical disinfection	
		EN ISO 15883-1 75°C - 30min	Glutaraldehyde 3.4% for 20 minutes	
Nasal mask	NM-03	√	√	15

High level thermal disinfection instruction is as below:

1. Using a certified hot water disinfection system, soak the mask components using a temperature-time combination:

EN ISO 15883-1:

- 75°C for 30minutes

2. Remove the mask components from the hot water disinfection system.
3. Air dry out of direct sunlight.

High level chemical disinfection instruction is as below:

1. Soak the mask components in glutaraldehyde 3.4% for 20 minutes.
2. Rinse thoroughly with drinking quality water(5 liters per mask) three times and air dry out of direct sunlight.

Inspection : Perform a visual inspection of each mask component. If any visible deterioration of a mask component is apparent (cracking, crazing, tears etc), the mask component should be discarded and replaced. Slight discolouration of the silicone components may occur and is acceptable.

Caution: The Mask must be thoroughly cleaned prior to high level disinfection.

Reassembling the Mask

See section C on the illustrations sheet.

Before reassembling the mask, check that all components are clean and dry. Check that the valve is not damaged, distorted or torn, and that none of the other components are broken or cracked. Replace any parts that are damaged.

1. Insert the pick off port(Fig.C-1).
2. Insert the assembly elbow into the faceplate and fix the gasket(Fig.C-2).
3. Place the cushion around the edge of the mask faceplate(Fig.C-3).
4. Align the cushion clip with the mask faceplate. Push the cushion clip into the mask faceplate, ensuring that all three clips click into place(Fig.C-4, Fig.C-5).
5. Insert the forehead pad into the bracket(Fig.C-6).
6. Insert the bracket into the support arm assembly(Fig.C-7).
7. Insert the support arm assembly into the top faceplate(Fig.C-8).

Directions for Use:

1. Make sure the mask is within the expiration date. Tear the package and take out the mask.
2. Cover the mask on the patient's face and fasten with the headgear.
3. Connect the air hose of respiration equipment.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Wearing Methods:

1. Connect the headgear to the mask. Position the mask over your face, and press the mask cushion gently against your face, pull the headgear over your head.



2. Adjust the top and the bottom straps so that the mask is sitting gently on your face.



3. Fasten the mask.



Storage

The packaged masks should be stored in the corrosive gases free, well-ventilated room with $-5^{\circ}\text{C} \sim +50^{\circ}\text{C}$ of the ambient temperature, less than 85% of the relative humidity.

Disposal

The SKynector CPAP Masks does not contain any hazardous substances and may be disposed of with your normal household refuse.

Technical parameters:

Deliverable pressure range :4~30 cmH₂O

Pressure Drop cm H₂O (hPa):

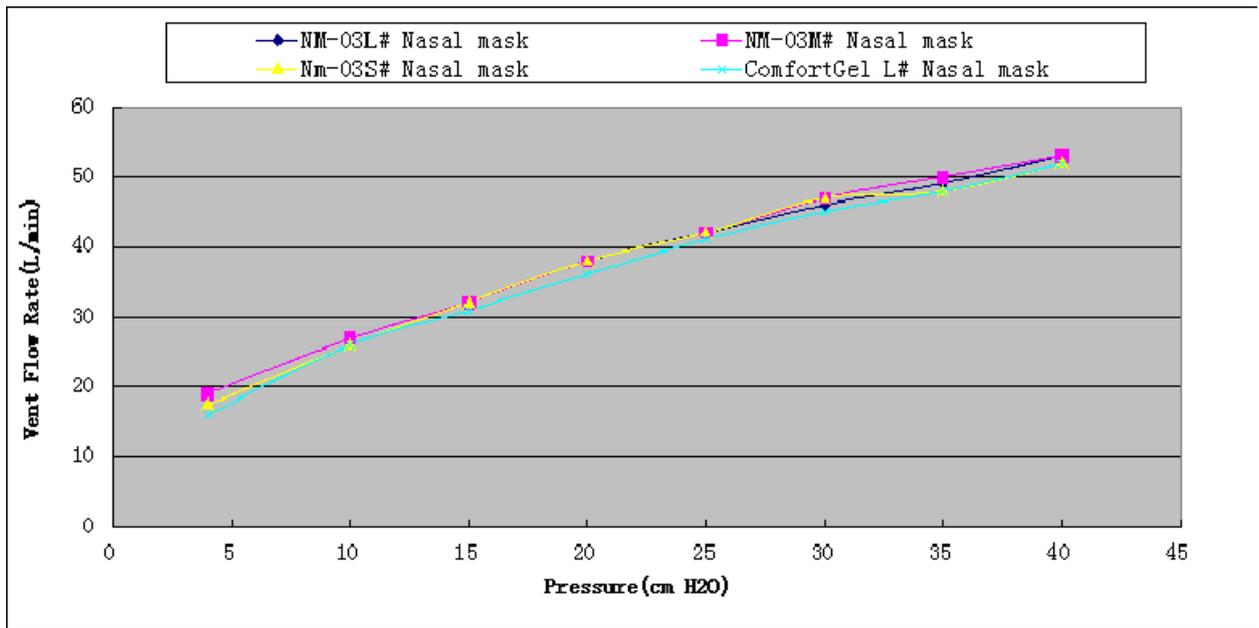
All mask size: 50 SLPM 2.5

100SLPM 8.5

Deadspace Volume

NM-03L 180mL NM-03M 160mL NM-03S 150mL

Pressure-flow curve



Sound

The A-weighted sound power of the mask is 35 dB.

Mask sizes

Size	length(mm)	width(mm)	height(mm)
L	157	106	90
M	155.5	105.5	89
S	155.5	96	90.5

Manufacturer: Sky Wise Medical Instrument (Shenzhen) Co., Ltd.

Address: No 12 South Ping Xi Road Xinsheng Community, Longgang Street, Longgang District, Shenzhen, Guangdong, China

Contact person: Hu hanhan
TEL: +86-755-28491103
FAX: +86-755-28494339
E-Mail: 942526346@qq.com



Full-face Mask FM-02
Quick Fitting Guide

- Connect top headgear
- Position the mask
- Connect bottom headgear
- Adjust
- Adjust
- Finish

CPAP Masks (Full-Face Masks)

Style/Size: FM-02 L FM-02 M FM-02 S

此处贴对应型号的条码标签

(See the seal)

Sky Wise Medical Instrument (ShenZhen) CO., LTD
Address: No. 12 South PingXi Road Xinheng Community, LongGang Street, LongGang District, ShenZhen

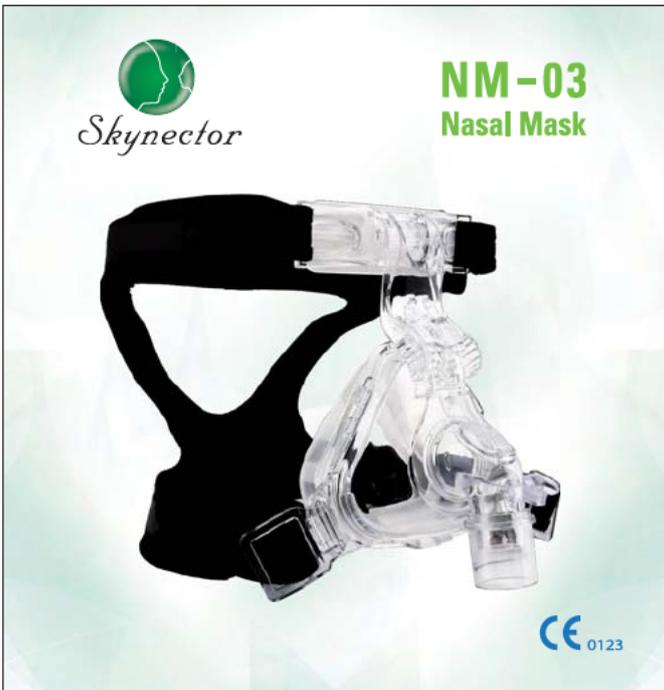
Wellbeing Ltd
Suite 19, 20 Harley St. W1D 3HQ, LONDON W1G 8QR, England, United Kingdom

Rx only

(See the seal)

<< www.skynector.com

Made in china



Nasal Mask NM-03

Quick Fitting Guide

-  Connect top headgear
-  Position the mask
-  Connect bottom headgear
-  Adjust
-  Adjust
-  Finish

CPAP Masks (Nasal Masks)

Style/Size: NM-03 L NM-03 M NM-03 S

  此处贴对应型号的条码标签 

 Get the Lot

 **Rx only**  (See the label)

 << www.skynector.com Made in china



Shelf Life

1. Summary

The Skynector CPAP Mask is a prescription device supplied non-sterile. For the Non-sterile mask or reuse mask, it should be cleaned before use. As the CPAP mask is made of plastic, Sky Wise has conducted an (b)(4) test for the shelf life of the CPAP mask, according to ASTM D3045: 1992 Standard Practice for Heat Aging of Plastics without Load. The result shows the CPAP mask's expiration date 2 years is reliable.

2. Cleaning of the CPAP mask

2.1 Daily/After Each use

For the non-sterile mask or reuse mask, it need a hand wash prior to first use or daily, and the headgear should be hand washed weekly or when needed. The cleaning instruction is as below:

- a. Hand wash the mask in warm (30°C) water with a mild liquid dish washing detergent.
Caution: Do not use bleach, alcohol, cleaning solutions containing bleach or alcohol, or cleaning solutions containing conditioners or moisturizers.
- b. Rinse thoroughly with drinking quality water and air dry out of direct sunlight. Make sure the mask is dry before use. Lay the headgear at or line dry. Do not place the headgear into the dryer.
- c. Inspect the mask. If any parts are damaged or can not be cleaned, replace the mask.

2.2 Reprocessing the Mask between Patients

The mask should be reprocessed when used between patients. The cleaning and disinfection instructions are as below:

Table 01 SkyWise validated disinfection procedures

The CPAP mask		SkyWise validated disinfection procedures		Validated number of cycles
		High level thermal disinfection	High level chemical disinfection	
		75°C - 30min	Glutaraldehyde 3.4% for 20 minutes	
The full-mask	FM-02	√	√	15
The Nasal-mask	NM-03	√	√	15

3 (b)(4) test for CPAP Mask

3.1 The basis of the test:

(b)(4)

Sky Wise Medical Instrument (Shenzhen) Co., Ltd.

(b)(4) _Cover Letter

Product: Skynector CPAP Mask

Version (b)

K150685 S001

Cover Letter for 510(k) S001

Dear FDA reviewer:

Thank you for reviewing 510(k) submission, K150685, and I am grateful to you for making the comments on it. The supplementary information requested had been prepared and sent to you.

The eCopy of the additional information had been sent along with the hard copy, I state here:

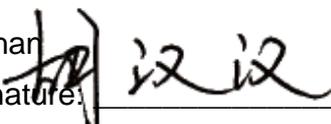
eCopy Statement

Per the instructions accessed at <http://www.fda.gov/cdrh/electsub.html>, an electronic copy is being provided with this submission and it is an exact duplicate of the original paper submission.

Please let me know if you have any questions or concerns, please feel free to contact me with E-mail or Fax. Thanks!

Sincerely Yours,

Management Representative: Hu hanhan

Signature: 

Date: 2015, May, 04.

FDA CDRH DMC

JUL 23 2015

Sky Wise Medical Instrument (Shenzhen) Co., Ltd **Received** (b)(4) Cover Letter

Product: Skyneator CPAP Mask Version: (b)(4)

K150685/S003

K150685 S003

Cover Letter for 510(k) S002

Dear FDA reviewer:

Thank you for reviewing 510(k) submission, K150685, and I am grateful to you for making the comments on it. The supplementary information requested had been prepared and sent to you.

The eCopy of the additional information had been sent along with the hard copy, I state here:

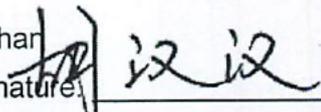
eCopy Statement

Per the instructions accessed at <http://www.fda.gov/cdrh/electsub.html>, an electronic copy is being provided with this submission and it is an exact duplicate of the original paper submission.

Please let me know if you have any questions or concerns, please feel free to contact me with E-mail or Fax. Thanks!

Sincerely Yours,

Management Representative: Hu hanhan

Signature: 

Date: 2015, July, 17.

Sky Wise Medical Instrument (Shenzhen) Co., Ltd.

(b)(4) _Cover Letter

Product: Skynector CPAP Mask

Version (b)

K150685 S002

Cover Letter for 510(k) S002

Dear FDA reviewer:

Thank you for reviewing 510(k) submission, K150685, and I am grateful to you for making the comments on it. The supplementary information requested had been prepared and sent to you.

The eCopy of the additional information had been sent along with the hard copy, I state here:

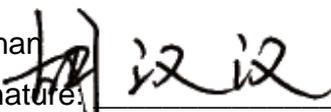
eCopy Statement

Per the instructions accessed at <http://www.fda.gov/cdrh/electsub.html>, an electronic copy is being provided with this submission and it is an exact duplicate of the original paper submission.

Please let me know if you have any questions or concerns, please feel free to contact me with E-mail or Fax. Thanks!

Sincerely Yours,

Management Representative: Hu hanhan

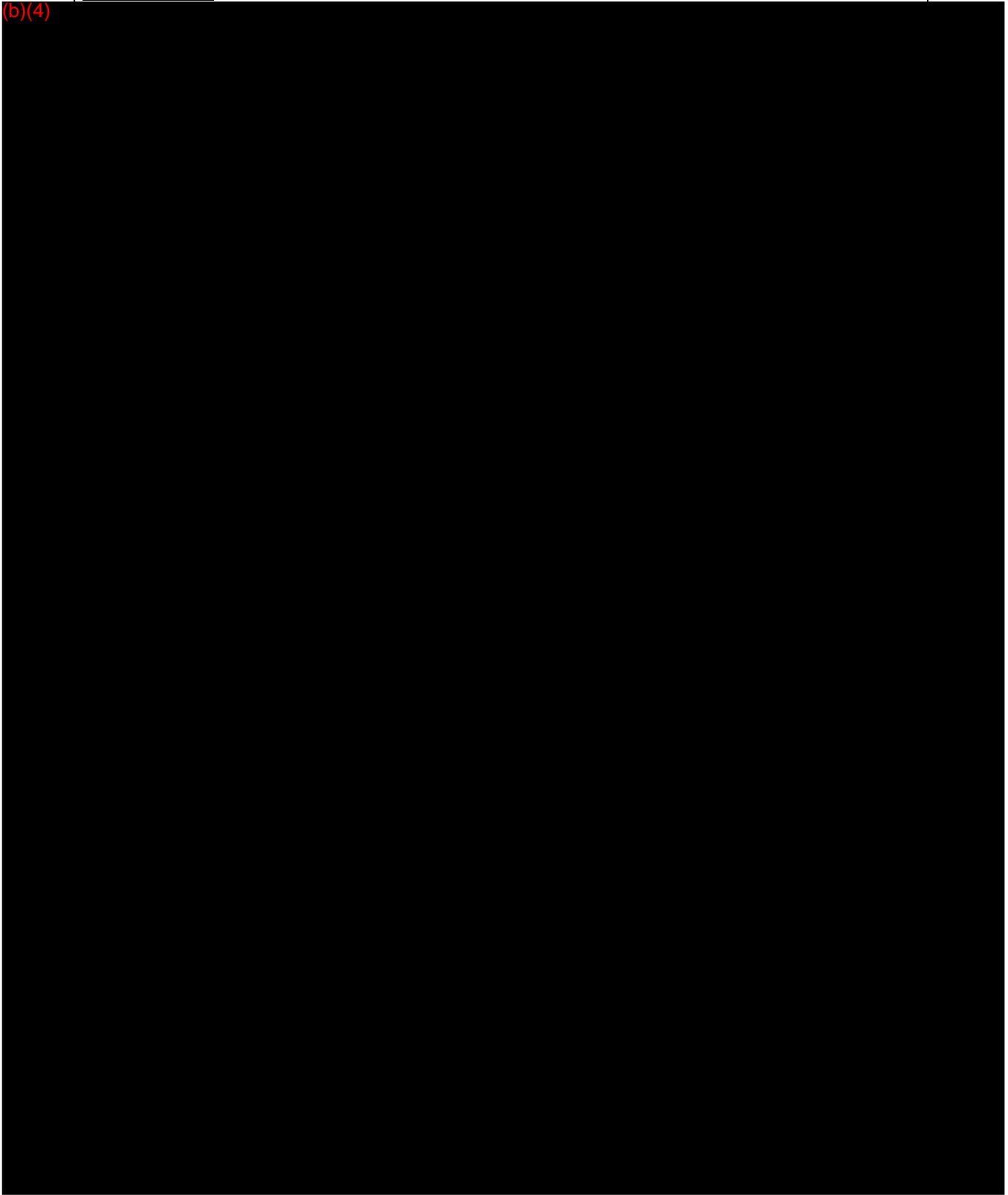
Signature: 

Date: 2015, July, 17.

The responses to Additional Information for K150685:

(b)(4) **Deficiencies**

(b)(4)



July, 17, 2015



Instruction For Use

FM-02 Series CPAP Full-Face Mask

User Guide

English

Skynector CPAP

FM-02 Full-Face Mask

Thank you for choosing Skynector CPAP Full-Face Mask.

The Skynector CPAP Full-Face Mask is a system that covers your nose and mouth. This means that you can receive effective therapy even if you breathe through your mouth. The mask incorporates vent holes and a built-in valve so that you can continue to breathe fresh air if the airflow to your mask is impeded for any reason.

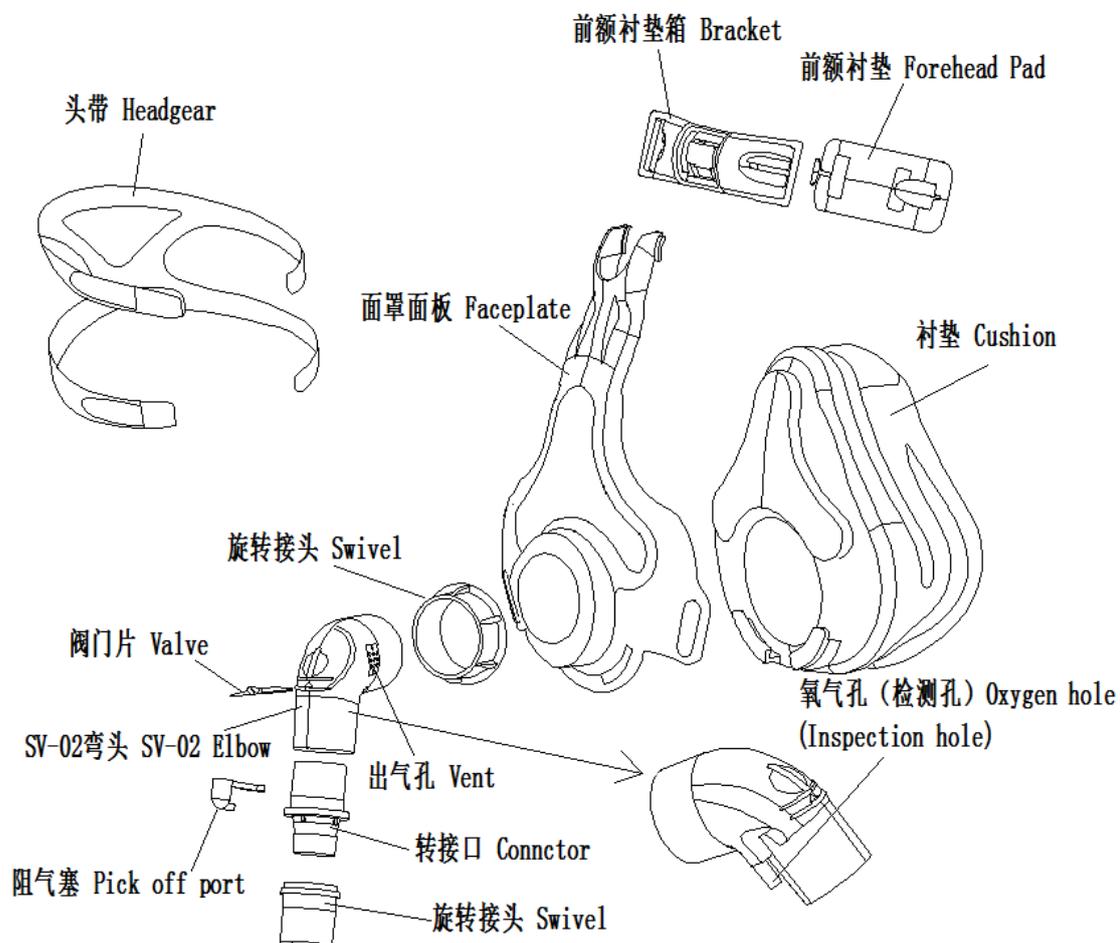
Intended Use/Indications for Use

The Skynector CPAP Mask channels airflow non-invasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system.

The Skynector CPAP Mask is to be used by adult patients (>66lb / >30kg) for whom positive airway pressure has been prescribed.

The Skynector CPAP Mask is intended for single patient re-use in the home environment and/or multi-patient reuse in the hospital /institutional environment.

Product composition



Item	Description	Part number
1	Bracket	3321004
2	forehead pad	3321020
3	Faceplate	3331103 (L) 3331101 (M)3331101 (S)
4	Cushion	3331004 (L) 3331002 (M) 3331012 (S)
5	Swivel I	3371006
6	Swivel II	3341003
7	Connector	3341013
8	Vent	—
9	Valve	3341015
10	Elbow	3341114
11	pick off port	3321013
12	Headgear	3321017
13	Headgear clip	3321019

Before Using the Mask

WARNINGS

1. This mask is not suitable for providing life support ventilation.
2. This mask is designed for use with CPAP or Bi-level systems recommended by your health care professional or respiratory therapist. Do not wear this mask unless the CPAP or Bi-level system is turned on and operating properly. Do not block or try to seal the vent holes.

Explanation of the Warning: CPAP systems are intended to be used with special masks with connectors which have vent holes to allow continuous flow of air out of the mask. When the CPAP machine is turned on and functioning properly, new air from the CPAP machine flushes the exhaled air out through the attached mask exhalation port. However, when the CPAP machine is not operating, enough fresh air will not be provided through the mask, and exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can in some circumstances lead to suffocation. This warning applies to most models of CPAP systems.

3. If oxygen is used with the device, the oxygen flow must be turned off when the device is not operating. Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.
4. At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, mask selection, and the leak rate. This warning applies to most types of CPAP and Bi-level

machines.

5. At low CPAP pressures the flow through the vent holes may be inadequate to clear all exhaled gas from the tubing. Some rebreathing may occur.

6. This product may contain chemicals (phthalates) which may cause adverse reactions for the patients who are pregnant or lactational. Consult the health care professional before use.

7. Some users may experience skin redness, irritation, or discomfort. If this happens, discontinue use and contact your health care professional.

8. The patient's physician should be contacted if the patient experiences the following symptoms while using the mask or after removing it: Unusual chest discomfort, shortness of breath, stomach distension, belching, or severe headache; drying of the eyes, eye pain, or eye infections; blurred vision. (Consult an ophthalmologist if symptoms persist).

9. A minimum of 3cm H₂O (HPa) must be maintained when using this mask.

10. This mask is not recommended for patients who are taking a prescription drug that may cause vomiting.

11. Using a mask may cause tooth, gum, or jaw soreness or aggravate an existing dental condition. Consult your physician or dentist if symptoms occur.

Caution:

1. Do not use if the package is damaged.

2. Read and understand the instructions completely.

3. The mask is supplied as non-sterile. The mask needs to be washed with drinking quality water before first use.

4. Wash patient's face before use.

5. Check the size of the mask and the headgear.

6. The connector of this mask is conical 22mm and complies with the ISO 5356 standard. Check whether the outlet of the oxygen machine matches the mask before use.

7. Dispose of mask in accordance with local regulations.

Contraindications:

The masks should not be used if the patient is unresponsive or unable to remove the mask by themselves, and it is not recommended for patients who are taking a prescription drug that may cause vomiting.

Side effects:

Some users may experience skin redness, irritation, or discomfort. Some users may experience unusual chest discomfort, shortness of breath, stomach distension, belching, or severe headache; drying of the eyes, eye pain, or eye infections; blurred vision.

Disassembling the Mask:

Disassemble the mask by the following steps:



Step01:



Step02:



Step03:



Step04:



Step05:



Step06:



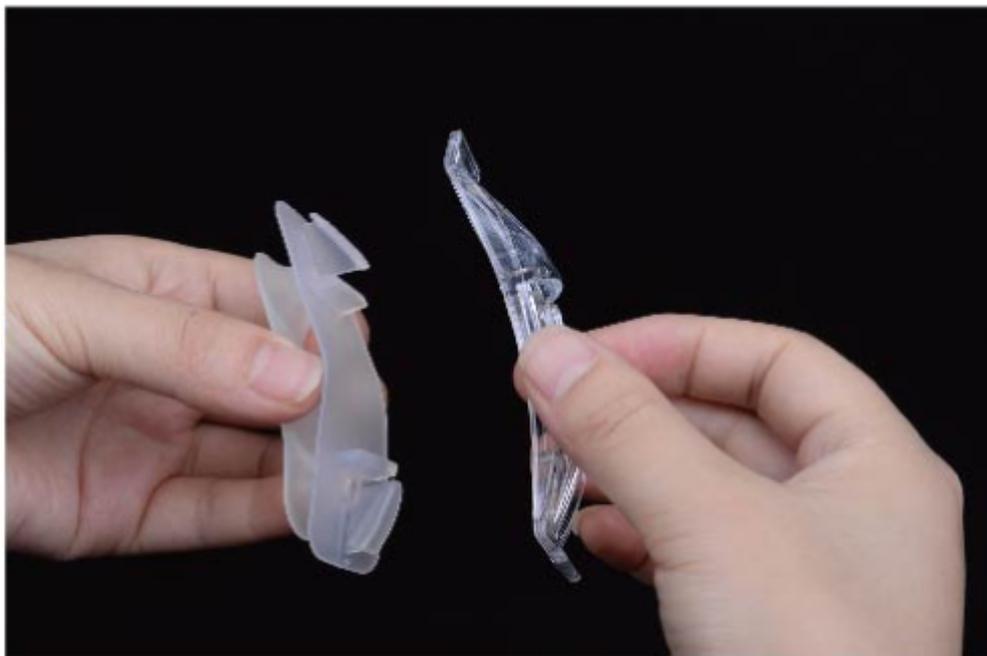
Step07:



Step08:



Step09:



Step10:



Step11:



Step12:



Step13:



Step14:



Step15:



Step16:

Cleaning of the CPAP mask

Daily/After Each use:

For the non-sterile mask or reuse mask, it need a hand wash prior to first use or daily, and the headgear should be hand washed weekly or when needed. The cleaning instruction is as below:

1. Cleaning the pick off port with a soft bristle brush for 1 minute while soaking in the detergent, Alconox (diluted 1%), paying particular attention to crevices and cavities. Caution: Do not use bleach, alcohol, cleaning solutions containing bleach or alcohol, or cleaning solutions containing conditioners or moisturizers.
2. Rinse thoroughly with drinking quality water (5 liters per mask) three times until clean and air dry out of direct sunlight. Make sure the mask is dry before use. Lay the headgear flat or line dry. Do not place the headgear into the dryer.
3. Inspect the mask. If any parts are damaged or can not be cleaned, replace the mask.

High Level Disinfection of the Mask between Patients

All mask components can be disinfected using validated procedures. The following presents a summary of the validated procedures for disinfection of the system. Refer to the website www.skynector.com for details or contacting Skywise Customer Service at +86 (0)755 28494331.

The CPAP mask		Sky Wise validated disinfection procedures		Validated number of cycles
		High level thermal disinfection	High level chemical disinfection	
		EN ISO 15883-1 75°C - 30min	Glutaraldehyde 3.4% for 20 minutes	
Full-face	FM-02	√	√	15

High level thermal disinfection instruction is as below:

1. Using a certified hot water disinfection system, soak the mask components using a temperature-time combination:

EN ISO 15883-1:

- 75°C for 30minutes
2. Remove the mask components from the hot water disinfection system.
 3. Air dry out of direct sunlight.

High level chemical disinfection instruction is as below:

1. Soak the mask components in glutaraldehyde 3.4% for 20 minutes.
2. Rinse thoroughly with drinking quality water(5 liters per mask) three times and air dry out of direct sunlight.

Inspection : Perform a visual inspection of each mask component. If any visible deterioration of a mask component is apparent (cracking, crazing, tears etc), the mask component should be discarded and replaced. Slight discolouration of the silicone components may occur and is acceptable.

Caution:

The mask should be reprocessed when used between patients, including thorough cleaning and disinfection;

The Mask must be thoroughly cleaned prior to high level disinfection.

Reassembling the Mask

Reassemble the Mask in the reverse order to the assembling, that is:



Step01:



Step02:



Step03:



Step04:



Step05:



Step06:



Step07:



Step08:



Step09:



Step10:



Step11:



Step12:



Step13:



Step14:



Step15:



Step16:

Before reassembling the mask, check that all components are clean and dry. Check that the valve is not damaged, distorted or torn, and that none of the other components are broken or cracked. Replace any parts that are damaged.

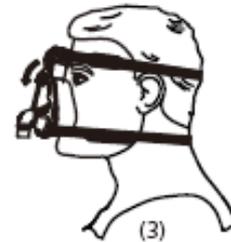
Directions for Use:

1. Make sure the mask is within the expiration date. Tear the package and take out the mask.
2. Cover the mask on the patient's face and fasten with the headgear.
3. Connect the oxygen hose to the oxygen supply.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Wearing Methods:

1. Connect the headgear to the mask. Position the mask over your face, and press the mask cushion gently against your face, pull the headgear over your head.
2. Adjust the top and the bottom straps so that the mask is sitting gently on your face.
3. Fasten the mask.



Technical parameters:

Deliverable pressure range :4~20 cmH₂O

Pressure Drop cm H₂O (hPa):

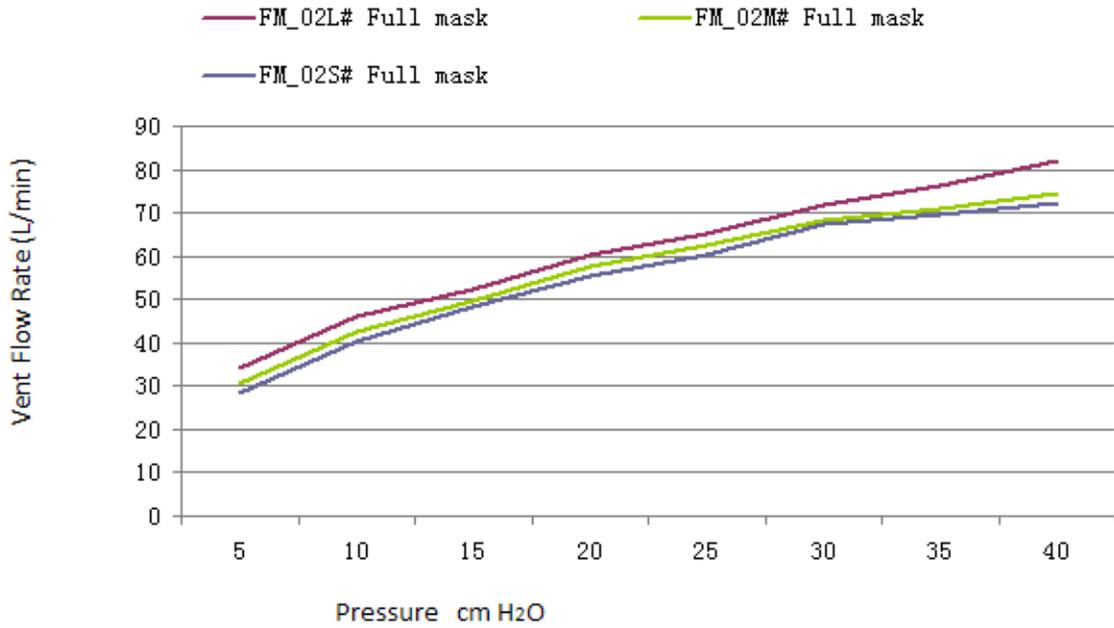
All mask size: 50 SLPM 0.5

100 SLPM 1.5

Deadspace Volume

FM-02L: 358mL; FM-02M: 311mL; FM-02S: 280mL

Pressure-flow curve



Open/close pressure for anti-asphyxia valve (cmH₂O):

Open pressure:2.0 close pressure:1.5

Storage

The packaged masks should be stored in the corrosive gases free, well- ventilated room with **-5°C(23°F)~+50°C(122°F)** of the ambient temperature, less than 85% of the relative humidity.

Mask sizes

Size	length(mm)	width(mm)	height(mm)
L	215	120.5	130
M	215	115.5	130
S	215	115.5	126

Manufacturer: Sky Wise Medical Instrument (Shenzhen) Co., Ltd.

Address: No 12 South Ping Xi Road Xinsheng Community, Longgang Street, Longgang District, Shenzhen, Guangdnog, China

Contact person: Hu hanhan
 TEL: +86-755-28491103
 FAX: +86-755-28494339
 E-Mail: 942526346@qq.com



Instruction For Use

NM-03 Series CPAP Nasal Mask

User Guide

English

Skynector CPAP

NM-03 Nasal Mask

Thank you for choosing Skynector CPAP Nasal Mask.

The Skynector CPAP Nasal Mask is a system that covers your nose only. The mask incorporates vent holes to reduce carbon dioxide rebreathing.

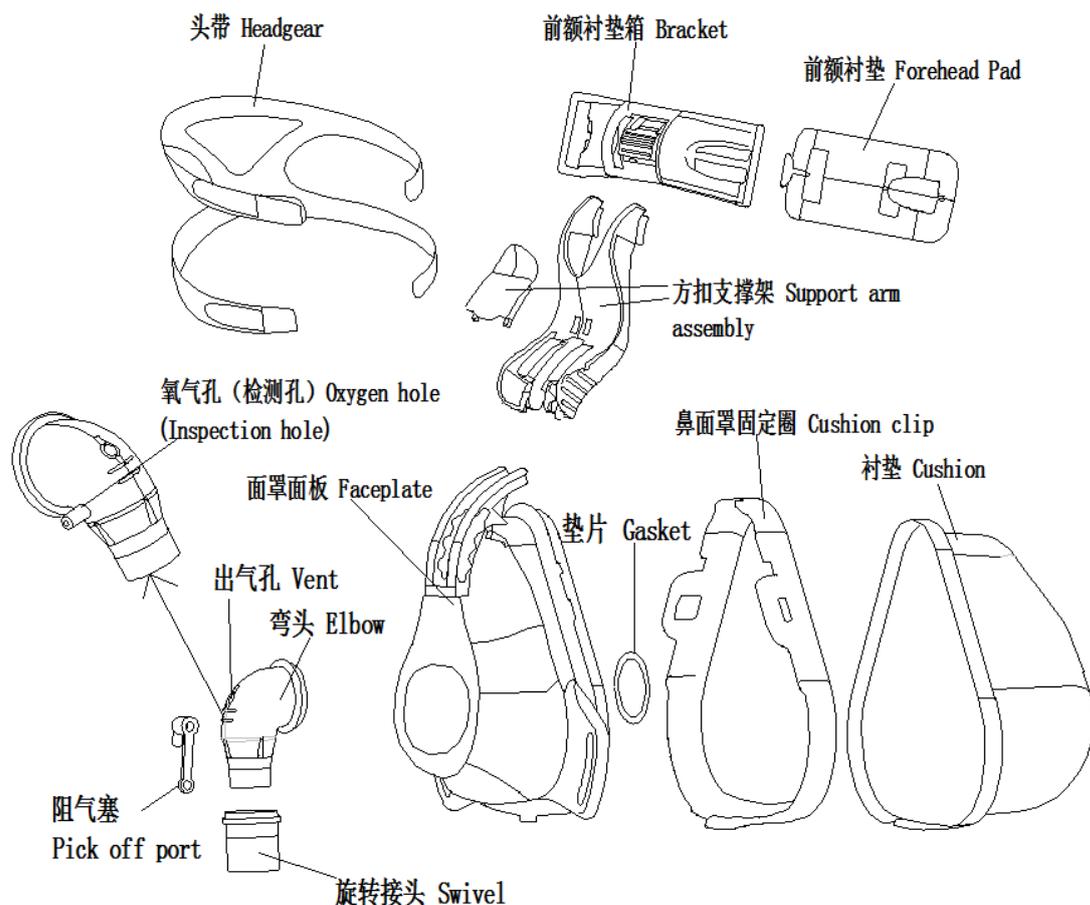
Intended Use/Indications for Use

The Skynector CPAP Mask channels airflow non-invasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system.

The Skynector CPAP Mask is to be used by adult patients (>66lb / >30kg) for whom positive airway pressure has been prescribed.

The Skynector CPAP Mask is intended for single patient re-use in the home environment and/or multi-patient reuse in the hospital /institutional environment.

Product composition



Item	Description	Part number
1	Faceplate	3461001 (L) 3461001 (M) 3461005 (S)
2	Cushion clip	3461002 (L) 3461002 (M) 3461006 (S)
3	Cushion	3461003 (L) 3461004 (M) 3461007 (S)
4	support arm assembly	3361015
5	forehead pad	3321020
6	Bracket	3321004
7	Swivel	3371006
8	Vent	—
9	Gasket	3321014
10	Elbow	3371005
11	pick off port	3321013
12	Headgear	3321017
13	Headgear clip	3321019

Before Using the Mask



WARNINGS

1. This mask is not suitable for providing life support ventilation.
2. This mask is designed for use with CPAP or Bi-level systems recommended by your health care professional or respiratory therapist. Do not wear this mask unless the CPAP or Bi-level system is turned on and operating properly. Do not block or try to seal the vent holes.

Explanation of the Warning: CPAP systems are intended to be used with special masks with connectors which have vent holes to allow continuous flow of air out of the mask. When the CPAP machine is turned on and functioning properly, new air from the CPAP machine flushes the exhaled air out through the attached mask exhalation port. However, when the CPAP machine is not operating, enough fresh air will not be provided through the mask, and exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can in some circumstances lead to suffocation. This warning applies to most models of CPAP systems.

3. If oxygen is used with the device, the oxygen flow must be turned off when the device is not operating. Oxygen supports combustion. Oxygen should not be used

while smoking or in the presence of an open flame.

4. At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, mask selection, and the leak rate. This warning applies to most types of CPAP and Bi-level machines.

5. At low CPAP pressures the flow through the vent holes may be inadequate to clear all exhaled gas from the tubing. Some rebreathing may occur.

6. This product may contain chemicals (phthalates) which may cause adverse reactions for the patients who are pregnant or lactational. Consult the healthcare professional before use.

7. Some users may experience skin redness, irritation, or discomfort. If this happens, discontinue use and contact your health care professional.

8. The patient's physician should be contacted if the patient experiences the following symptoms while using the mask or after removing it: unusual chest discomfort, shortness of breath, stomach distension, belching, or severe headache; drying of the eyes, eye pain, or eye infections; blurred vision. (Consult an ophthalmologist if symptoms persist).

9. A minimum of 3cm H₂O (HPa) must be maintained when using this mask.

10. This mask is not recommended for patients who are taking a prescription drug that may cause vomiting.

11. Using a mask may cause tooth, gum, or jaw soreness or aggravate an existing dental condition. Consult your physician or dentist if symptoms occur.

Caution:

1. Do not use if the package is damaged.

2. Read and understand the instructions completely.

3. The mask is supplied as non-sterile. The mask needs to be washed with drinking quality water before first use.

4. Wash patient's face before use.

5. Check the size of the mask and the headgear.

6. The connector of this mask is conical 22mm and complies with the ISO 5356 standard. Check whether the outlet of the oxygen machine matches the mask before use.

7. Dispose of mask in accordance with local regulations.

Contraindications:

The masks should not be used if the patient is unresponsive or unable to remove the mask by themselves, and it is not recommended for patients who are taking a prescription drug that may cause vomiting.

Side effects:

Some users may experience skin redness, irritation, or discomfort. Some users may experience unusual chest discomfort, shortness of breath, stomach distension, belching, or severe headache; drying of the eyes, eye pain, or eye infections; blurred vision.

Disassembling the Mask:

Disassemble the mask by the following steps:



Step01:



Step02:



Step03:



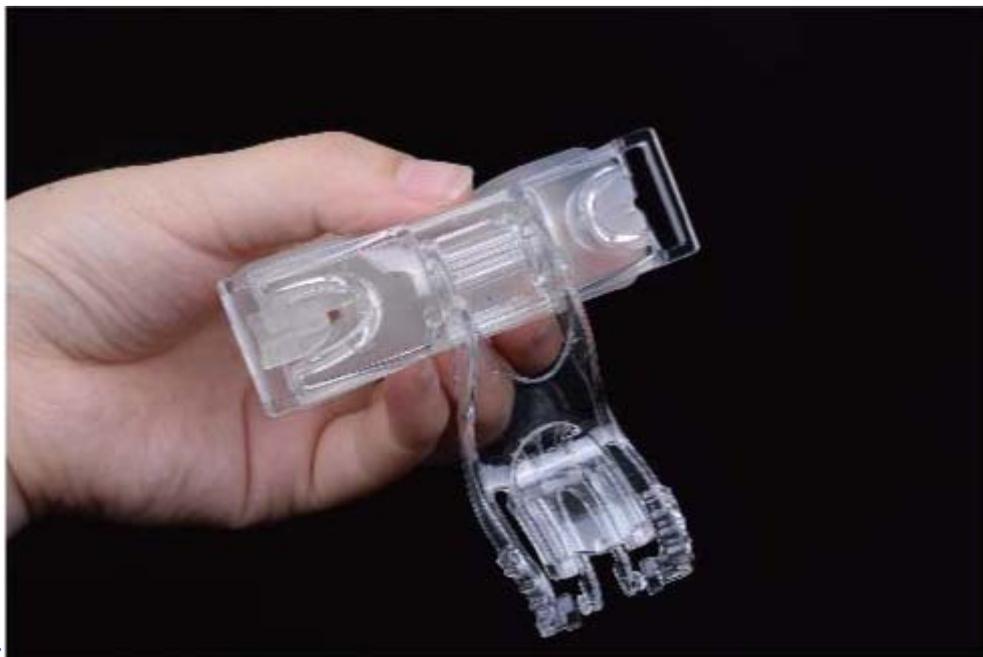
Step04:



Step05:



Step06:



Step07:



Step08:



Step09:



Step10:



Step11:



Step12:



Step13:



Step14:



Step15:



Step16:

Cleaning of the CPAP mask

Daily/After Each use:

For the non-sterile mask or reuse mask, it needs a hand wash prior to first use or daily, and the headgear should be hand washed weekly or when needed. The cleaning instruction is as below:

1. Cleaning the pick off port with a soft bristle brush for 1 minute while soaking in the detergent, Alconox (diluted 1%), paying particular attention to crevices and cavities.
Caution: Do not use bleach, alcohol, cleaning solutions containing bleach or alcohol, or cleaning solutions containing conditioners or moisturizers.
2. Rinse thoroughly with drinking quality water(5 liters per mask) three times until clean and air dry out of direct sunlight. Make sure the mask is dry before use. Lay the headgear flat or line dry. Do not place the headgear into the dryer.
3. Inspect the mask. If any parts are damaged or can not be cleaned, replace the mask.

High Level Disinfection of the Mask between Patients

All mask components can be disinfected using validated procedures. The following presents a summary of the validated procedures for disinfection of the system. Refer to the website www.skynector.com for details or contacting Sky Wise Customer Service at +1-800-XXX-XXX. (Please note that, we have applied for the toll-free number and will include it once we have received it.)

The CPAP mask		Sky Wise validated disinfection procedures		Validated number of cycles
		High level thermal disinfection	High level chemical disinfection	
		EN ISO 15883-1 75°C - 30min	Glutaraldehyde 3.4% for 20 minutes	
Nasal mask	NM-03	✓	✓	15

High level thermal disinfection instruction is as below:

1. Using a certified hot water disinfection system, soak the mask components using a temperature-time combination:

EN ISO 15883-1:

- 75°C for 30minutes

2. Remove the mask components from the hot water disinfection system.
3. Air dry out of direct sunlight.

High level chemical disinfection instruction is as below:

1. Soak the mask components in glutaraldehyde 3.4% for 20 minutes.
2. Rinse thoroughly with drinking quality water(5 liters per mask) three times and air dry out of direct sunlight.

Inspection : Perform a visual inspection of each mask component. If any visible deterioration of a mask component is apparent (cracking, crazing, tears etc), the mask component should be discarded and replaced. Slight discolouration of the silicone components may occur and is acceptable.

Caution:

The mask should be reprocessed when used between patients, including thorough cleaning and disinfection;

The Mask must be thoroughly cleaned prior to high level disinfection.

Reassembling the Mask

Reassemble the Mask in the reverse order to the assembling, that is:



Step01:



Step02:



Step03:



Step04:



Step05:



Step06:



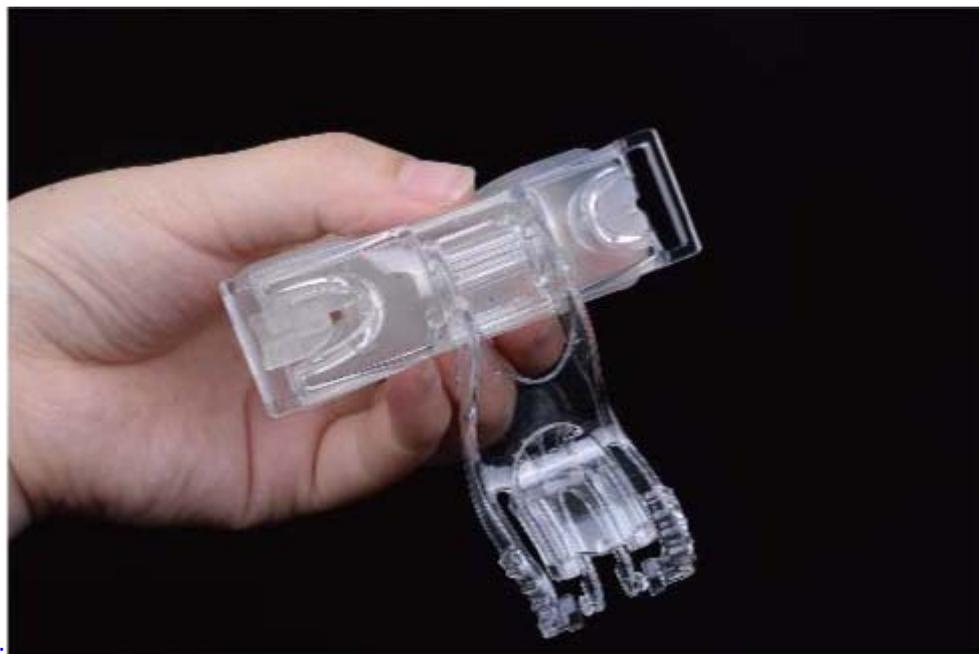
Step07:



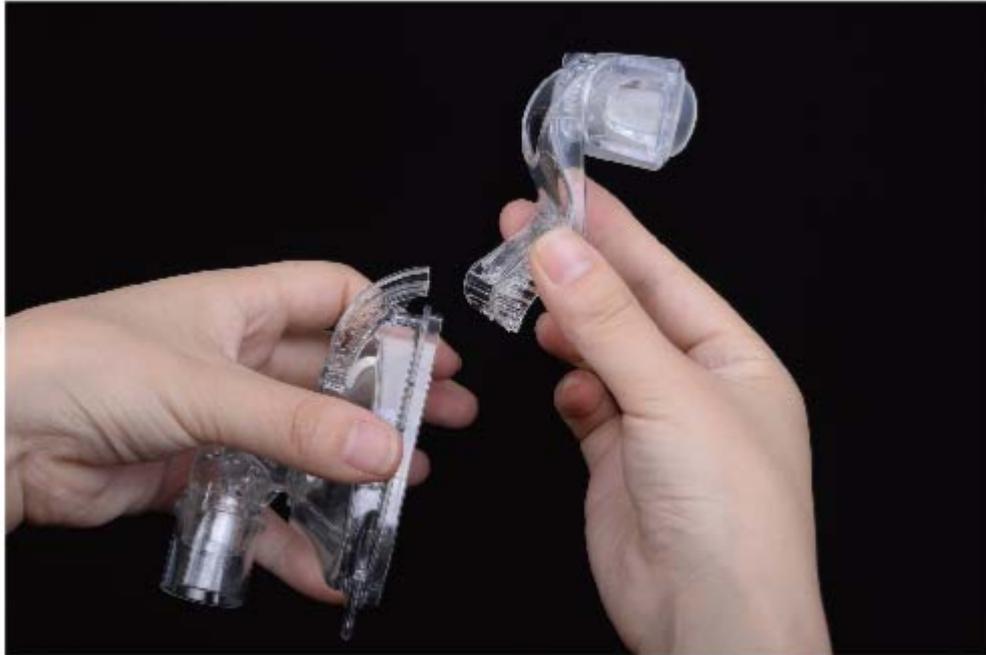
Step08:



Step09:



Step10:



Step11:



Step12:



Step13:



Step14:



Step15:



Step16:

Before reassembling the mask, check that all components are clean and dry. Check that the valve is not damaged, distorted or torn, and that none of the other components are broken or cracked. Replace any parts that are damaged.

Directions for Use:

1. Make sure the mask is within the expiration date. Tear the package and take out the mask.
2. Cover the mask on the patient's face and fasten with the headgear.
3. Connect the air hose of respiration equipment.

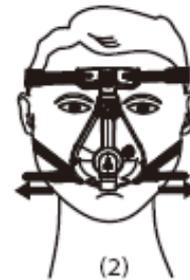
Caution: Federal law restricts this device to sale by or on the order of a physician.

Wearing Methods:

1. Connect the headgear to the mask. Position the mask over your face, and press the mask cushion gently against your face, pull the headgear over your head.



2. Adjust the top and the bottom straps so that the mask is sitting gently on your face.



3. Fasten the mask.



Storage

The packaged masks should be stored in the corrosive gases free, well-ventilated room with $-5^{\circ}\text{C}(23^{\circ}\text{F})\sim+50^{\circ}\text{C}(122^{\circ}\text{F})$ of the ambient temperature, less than 85% of the relative humidity.

Disposal

The SKynector CPAP Masks does not contain any hazardous substances and may be disposed of with your normal household refuse.

Technical parameters:

Deliverable pressure range : 4~30 cmH₂O

Pressure Drop cm H₂O (hPa):

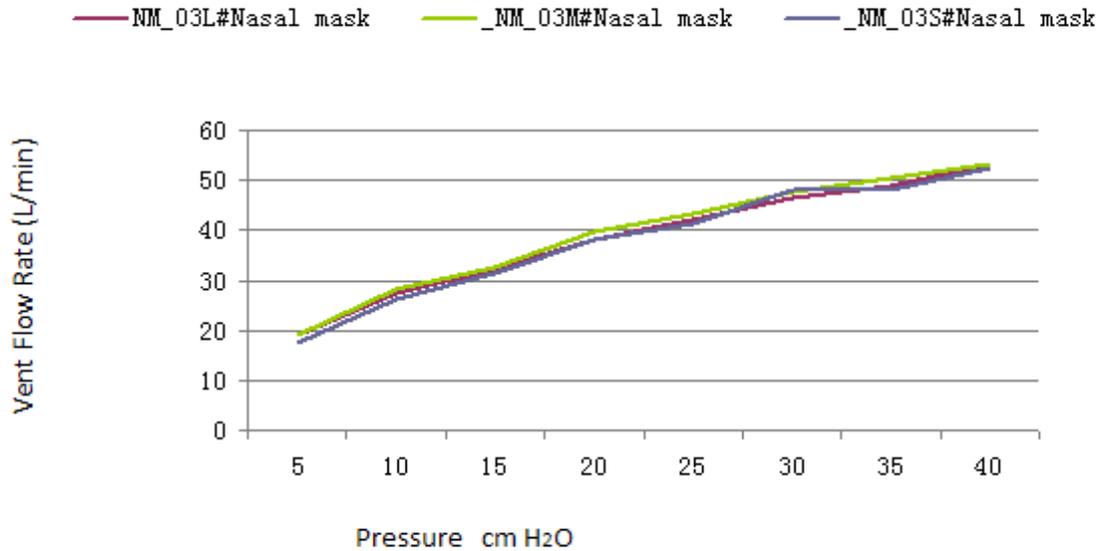
All mask size: 50 SLPM 2.5

100SLPM 8.5

Deadspace Volume

NM-03L 180mL NM-03M 160mL NM-03S 150mL

Pressure-flow curve



Sound

The A-weighted sound power of the mask is 35 dB.

Mask sizes

Size	length(mm)	width(mm)	height(mm)
L	157	106	90
M	155.5	105.5	89
S	155.5	96	90.5

Manufacturer: Sky Wise Medical Instrument (Shenzhen) Co., Ltd.

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