



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (kml)
FOLDER: K141770 - 2244 pages
COMPANY: 3B MEDICAL, INC (3BMEDI)
PRODUCT: VENTILATOR, NON-CONTINUOUS (RESPIRATOR) (BZD)
SUMMARY: Product: LUNA CPAP AND AUTO-CPAP SYSTEM

DATE REQUESTED: Dec 2, 2015

DATE PRINTED: Dec 2, 2015

Note: Printed



FDA CDRH DMC

AUG 27 2014

Received

3B™ Medical, Inc.

info@3BProducts.com

863-226-6285

FAX 863-226-6284

August 26, 2014

Food & Drug Administration
Center for Device and Radiological Health
Document Control Center W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Correction
510(k) K141770
RESmart GII CPAP and Auto-CPAP

Dear Sir/Madam:

We previously submitted our Resubmission of the 510(k) application. However, by clerical error, two of the documents submitted were prior versions.

Enclosed herewith please find corrected documents. The documents to be replaced include:

- Description of Device Modification
- Indications for Use

The corrected documents are attached, and are furnished as both paper documents and eCopy.

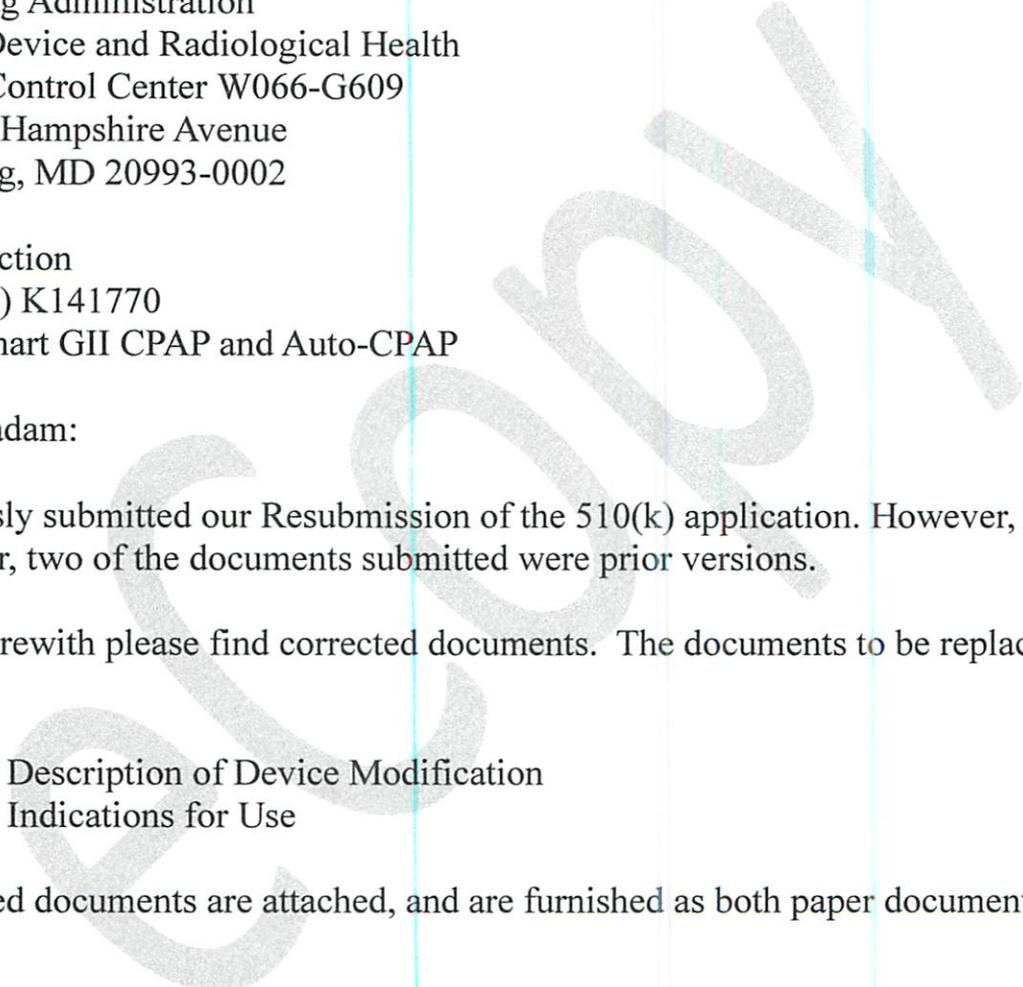
Sincerely,



Alex Lucio
Vice President

This eCopy is an exact duplicate of the paper copy.

K141770/A1



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Alex Lucio
Vice President

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K141770

Indications for Use

510(k) Number (if known)
K141770

Device Name

RESmart GII CPAP and Auto-CPAP System, also sold as LUNA CPAP and Auto-CPAP System

Indications for Use (Describe)

The 3B and BMC RESmart® GII (also sold as the Luna) CPAP and Auto-CPAP System Systems are intended to deliver positive pressure for the treatment of Obstructive Sleep Apnea. The optional integrated humidifier is indicated for the humidification and warming of air from the flow generator device. These devices are intended for single patient use by prescription in the home or hospital/institutional environment on adult patients.

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)

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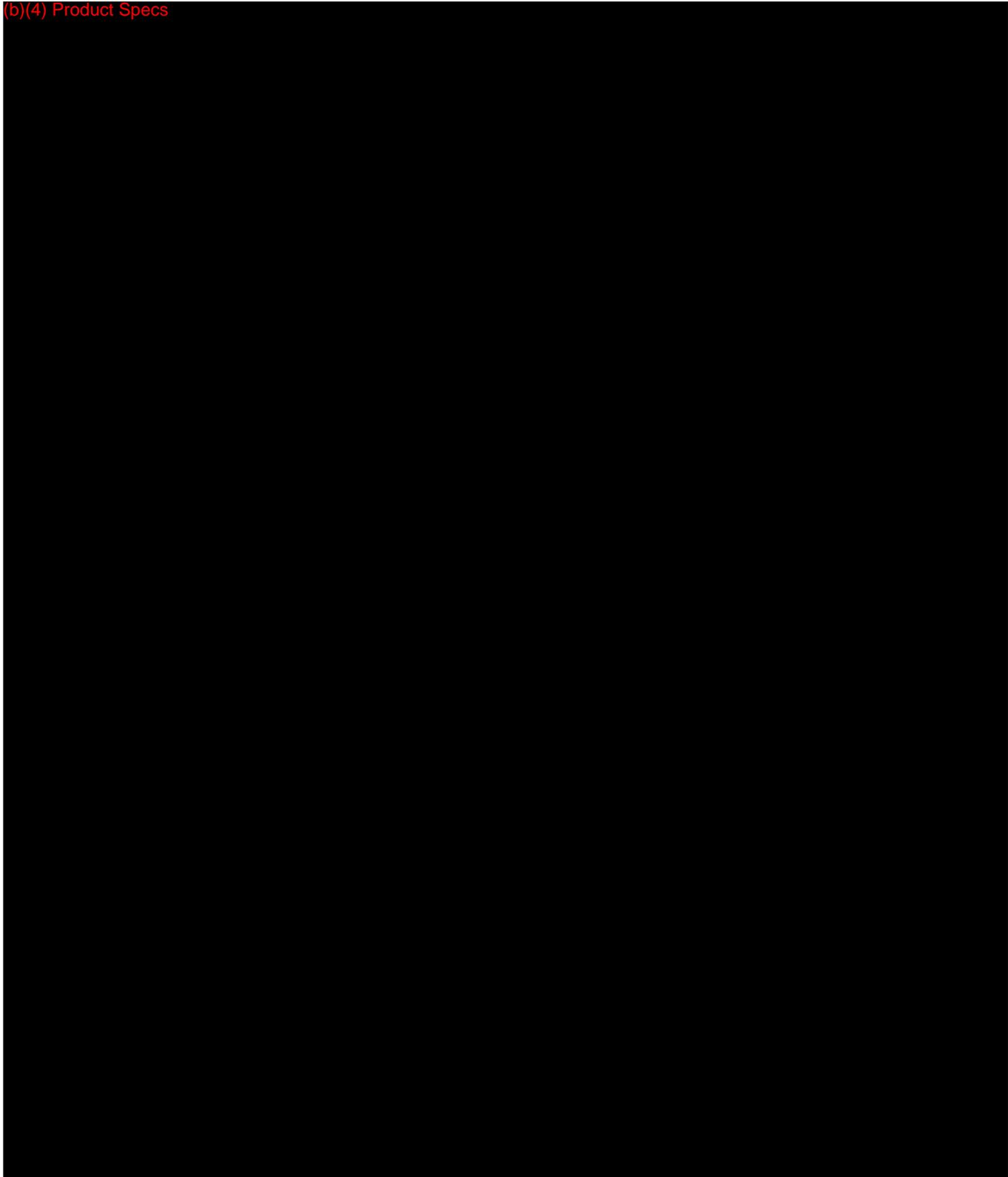
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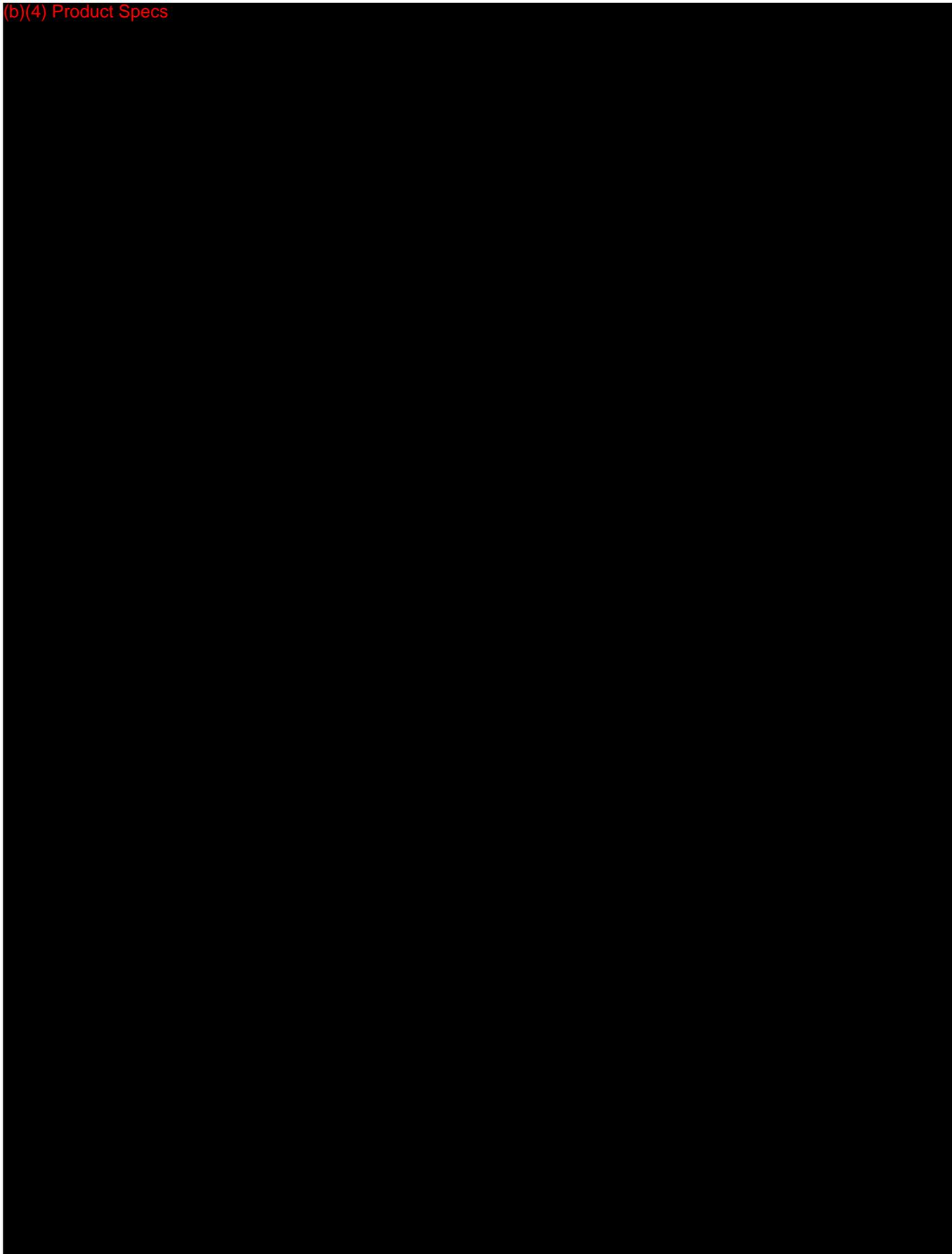
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Description of Device Modifications

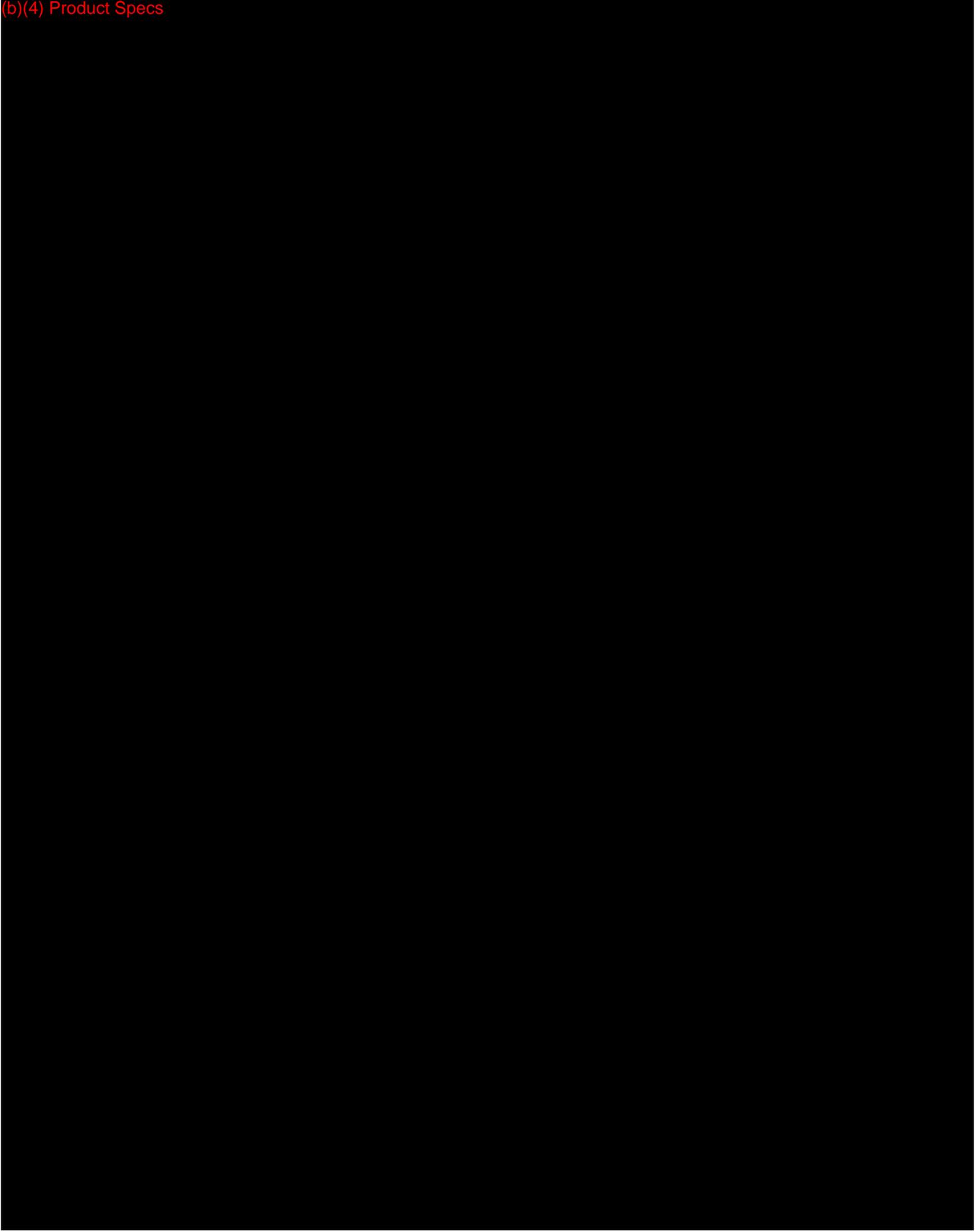
(b)(4) Product Specs



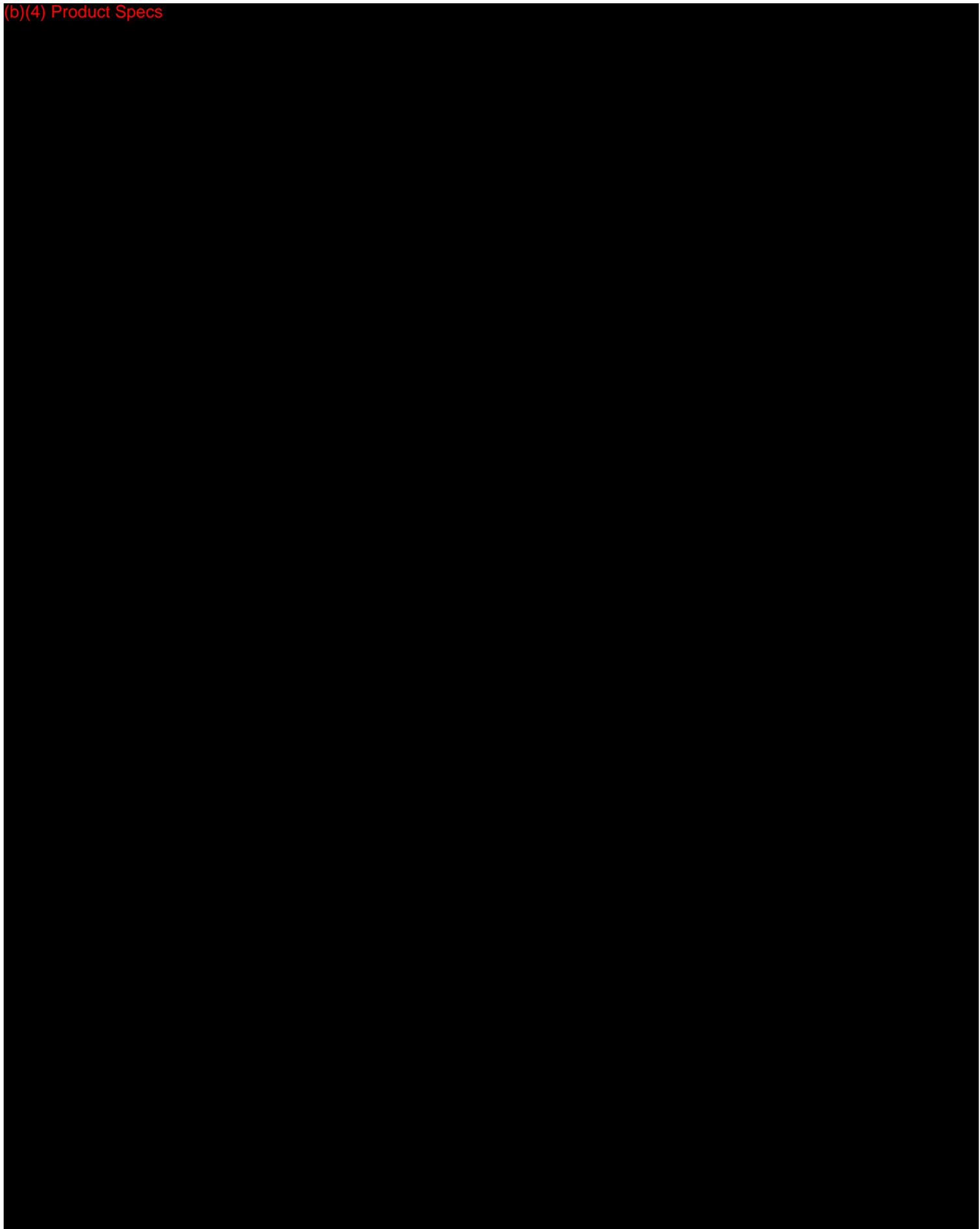
(b)(4) Product Specs



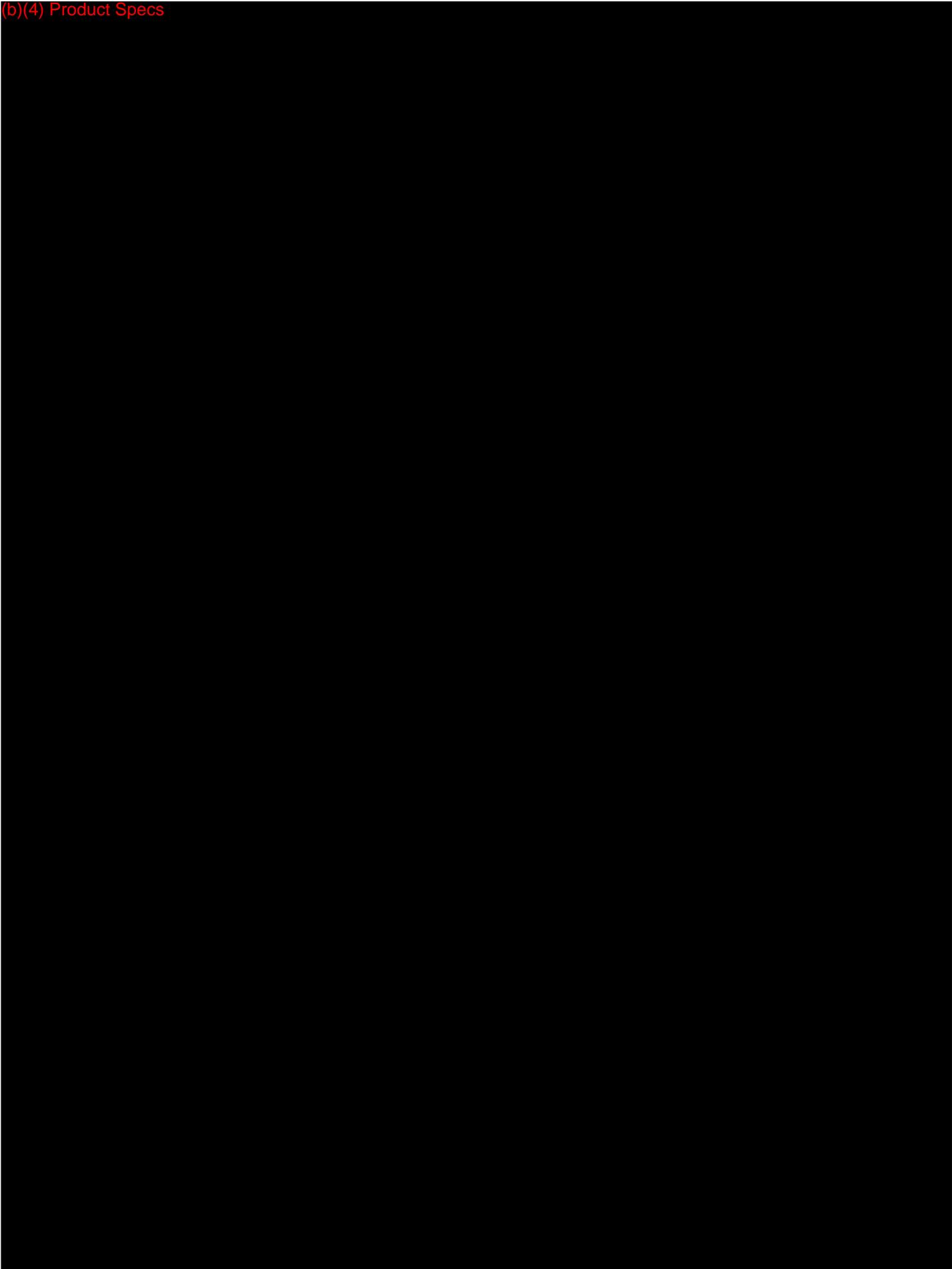
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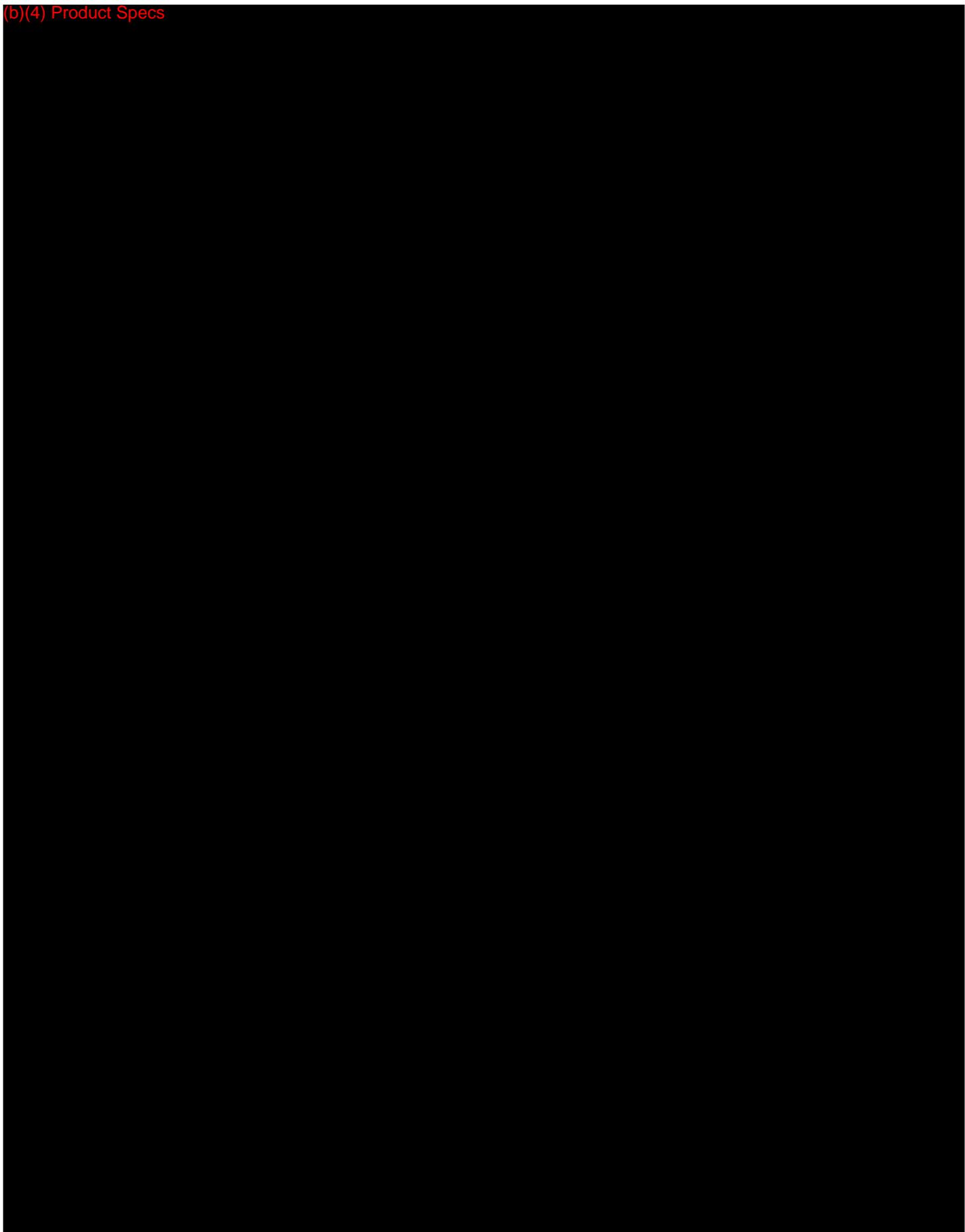
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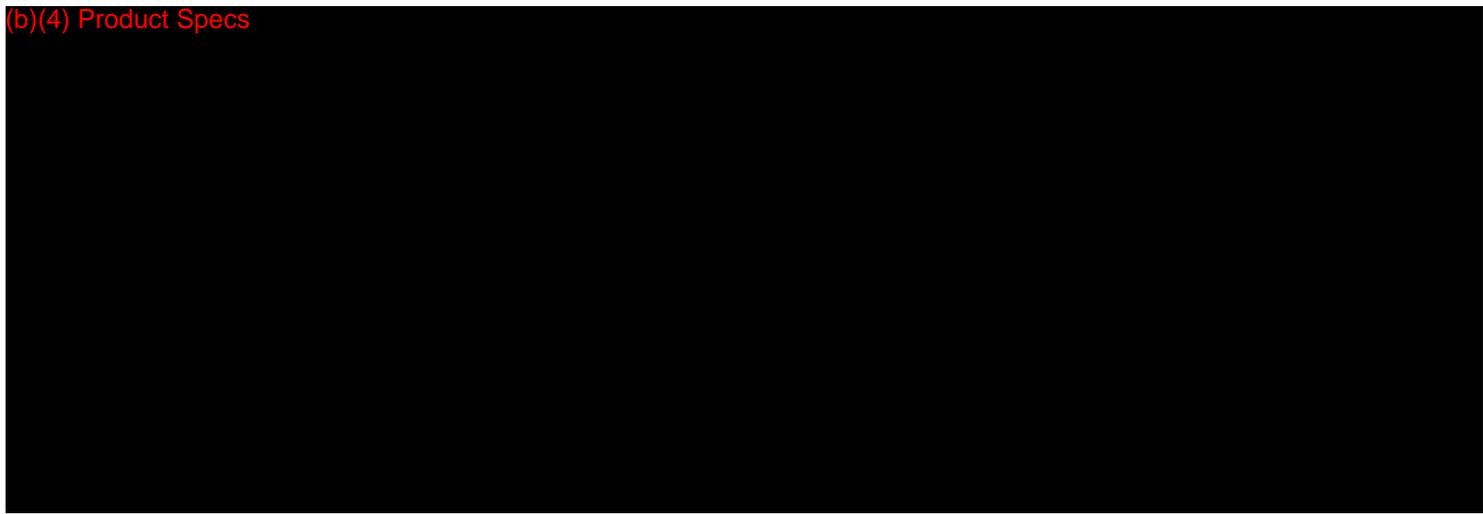
(b)(4) Product Specs



(b)(4) Product Specs



(b)(4) Product Specs



(b)(4) Product Specs



K141770

3B™ Medical, Inc.

FDA/CDRH/DCC

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JUL 01 2014

863-226-6285

FAX 863-226-6284

June 26, 2014

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Springs, MD 20993

RECEIVED



RE: SPECIAL 510(K)
RESmart GII CPAP and Auto-CPAP System,
also sold as LUNA CPAP and Auto-CPAP System

Dear Document Control Clerk:

3B Medical, Inc. hereby submits this Special 510(k): Device Modification for the RESmart CPAP and Auto-CPAP System. The predicate device for this Special 510(k) is the RESmart CPAP and Auto-CPAP System (K132967). The RESmart CPAP and Auto-CPAP devices proposed herein are being upgraded to include a redesigned enclosure and a larger color LCD with easier to use graphical user interface. Modifications to the product labelling and user manuals includes revisions necessary to conform to the user interface changes.

We consider our intent to market this device as confidential commercial information and request that FDA treat it as such. We have taken precautions to protect the confidentiality of the intent to market this device. We understand that submission of false information to the government is prohibited by 18 U.S.C. §1001 and 21 U.S.C. §331(q)

Thank you in advance for your consideration of this application. If you require additional information, please do not hesitate to contact me.

Sincerely

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Alex Lucio
Vice President

aal/dtg

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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: (b) (4) XXXXXXXXXX Write the Payment Identification number on your check.
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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>

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) 3B MEDICAL, INC. 21301 Hwy 27 N Lake Wales USA FL 33859 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****0396	2. CONTACT NAME Alex Lucio 2.1 E-MAIL ADDRESS alucio@3bproducts.com 2.2 TELEPHONE NUMBER (include Area code) 863-2266285 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 863-2266285
---	--

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><u>Select an application type:</u></p> <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> 30-Day Notice	<p>3.1 Select a center</p> <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER <p><u>3.2 Select one of the types below</u></p> <input checked="" type="checkbox"/> Original Application <p><u>Supplement Types:</u></p> <input type="checkbox"/> Efficacy (BLA) <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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4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

YES, I meet the small business criteria and have submitted the required qualifying documents to FDA NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number: SBD145281

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?

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.)

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)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

This application is the first PMA submitted by a qualified small business, including any affiliates

The sole purpose of the application is to support conditions of use for a pediatric population

This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE 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) [Redacted]

23-Jun-2014

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June 26, 2014

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Sincerely

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Alex Lucio
Vice President

aal/dtg

This eCopy is an exact duplicate of the paper copy.

Reviewer's Checklist

According to the "Draft DCRND Reviewer's Guidance for Premarket Notifications," November 1993, the following characteristics are identified:

- The RESmart CPAP and Auto CPAP System is not an implantable device.
- The RESmart CPAP and Auto CPAP System is not intended for life support or life sustaining applications.
- The RESmart CPAP and Auto CPAP System is not sold as sterile.
- The RESmart CPAP and Auto CPAP System is not a single-patient-use device.
- The RESmart CPAP and Auto CPAP System must be prescribed by a physician.
- The RESmart CPAP and Auto CPAP System does not contain a drug or biological product as a component.
- The RESmart CPAP and Auto CPAP System is not a kit.
- The RESmart CPAP and Auto CPAP System is software driven.
- The RESmart CPAP and Auto CPAP System is electrically operated.

Indications for Use

510(k) Number:

BMC RESmart® GII (also sold as the Luna) CPAP and Auto-CPAP System

Indications for Use:

The 3B and BMC RESmart® GII (also sold as the Luna) CPAP and Auto-CPAP SystemSystems are intended to deliver positive pressure for the treatment of Obstructive Sleep Apnea. The optional integrated humidifier is indicated for the humidification and warming of air from the flow generator device. These devices are intended for single patient use by prescription in the home or hospital/institutional environment on adult patients.

Prescription Use: X
(Part 21 CFR 801 Subpar D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Device Trade Name RESmart® GII (also sold as the Luna) CPAP and Auto-CPAP
Systems with Integrated Heated Humidifier

Common/Usual Name CPAP System, Auto-CPAP system

Date Prepared June 23, 2014

Sponsor Identification 3B Medical, Inc.
21301 Highway 27 N.
Lake Wales, FL 33859

Phone 863-226-6285
Fax 863-226-6284
Email alucio@3bproducts.com

Submission Correspondent Alex Lucio
3B Medical, Inc.
21301 Highway 27 N.
Lake Wales, FL 33859
Phone 863-226-6285
Fax 863-226-6284
Email alucio@3bproducts.com

Establishment Registration # 3008566132

BMC Medical CO., LTD
5/f Main Building No.19

510(k) Summary

Gucheng Street West, Shinjingshan
Beijing, CHINA 100043

Classification	Class II Device
Classification Panel	Medical Device
Classification Reference	21 CFR 878.5905
Products Code	BZD-Non-continuous Ventilator (Respirator)
Medical Specialties	Anesthesiology
Predicate Device(s)	RESmart® CPAP and Auto-CPAP Systems (K132967)
Reason for Submission:	Device Modification

Intended Use The 3B and BMC RESmart GII CPAP and AutoCPAP Systems are intended to deliver positive pressure for the treatment of Obstructive Sleep Apnea. The optional integrated humidifier is indicated for the humidification and warming of air from the flow generator device. These devices are intended for use by prescription in the home or hospital/institutional environment on adult patients.

Device Description The RESmart GII CPAP and AutoCPAP System is a microprocessor-controlled, blower-based system that generates positive airway pressure from 4 to 20 cm H₂O. The

510(k) Summary

device is intended for use with a patient interface (mask). The device has been modified to include a color LCD, easier to use menu driven user interface, and a redesigned enclosure. The electrical circuit was redesigned to incorporate the color LCD. The basic functionality and performance characteristic of the RESmart CPAP and AutoCPAP GII are unchanged from the predicate device RESmart CPAP and AutoCPAP (K132967).

Non-Clinical Testing

Extensive non-clinical testing was conducted in accordance with IOS 17510-1:2007. , Sleep Apnea Breathing Therapy-Part I: Sleep Apnea Breathing Therapy Equipment. Side by side Performance Bench Testing demonstrated substantial equivalence with the predicated device.

Materials used in the construction of components that contact the heated humidified gas pathway are classified as permanent “external communicating devices” (with tissue/bone/dentin). The appropriate biological tests conducted and passed for these components, in accordance with FDA guidance #G95-1-were:

- ISO 10993-3 Genotoxicity,
- ISO 10993-5 Cytotoxicity
- ISO 10993-6 Implantation and
- ISO 10993-10 Sensitization and Irritation

Testing for particulate matter and volatiles demonstrated compliance to EPA requirements

510(k) Summary

The RESmart GII has been tested to appropriate standards and other applicable requirements. The RESmart GII with integrated heated humidifier was designed and tested according to:

- IEC 60101-1:2005, Medical electrical equipment – Part 1: General Requirements for safety Medical electrical equipment – General requirements for basic safety and essential performance
- IEC 60601-1-2:2007, medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

The proposed and predicated devices have identical materials, indications for use, and operating principles. Testing and validation of component part upgrades establish substantial equivalence between predicate and proposed devices.

Substantial Equivalence The RESmart CPAP and AutoCPAP System (K132967) remain substantially equivalent to the proposed RESmart II CPAP and AutoCPAP/Luna CPAP and AutoCPAP System in that they have the same intended use, same operating principle, same technology, identical materials, and same manufacturing process. Designed validation and verification test were performed on the RESmart® GII (also sold as the Luna) CPAP

510(k) Summary

and Auto-CPAP System because of the risk analysis and product requirements.

Truthful Accuracy

A certification of truthfulness and accuracy of the RESmart® GII (also sold as the Luna) CPAP and Auto-CPAP System as described in this submission is provided in this submission is provided in Attachment 8.

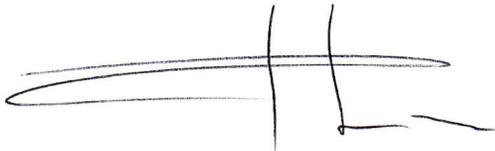
Conclusions

There have been no changes in the material composition, intended use, or operating principles. Validation and verification that the proposed device is substantially equivalent to the predicate device.

Premarket Notification and Accuracy Statement

[As required by 21 CFR Sec. 808.87 (k)]

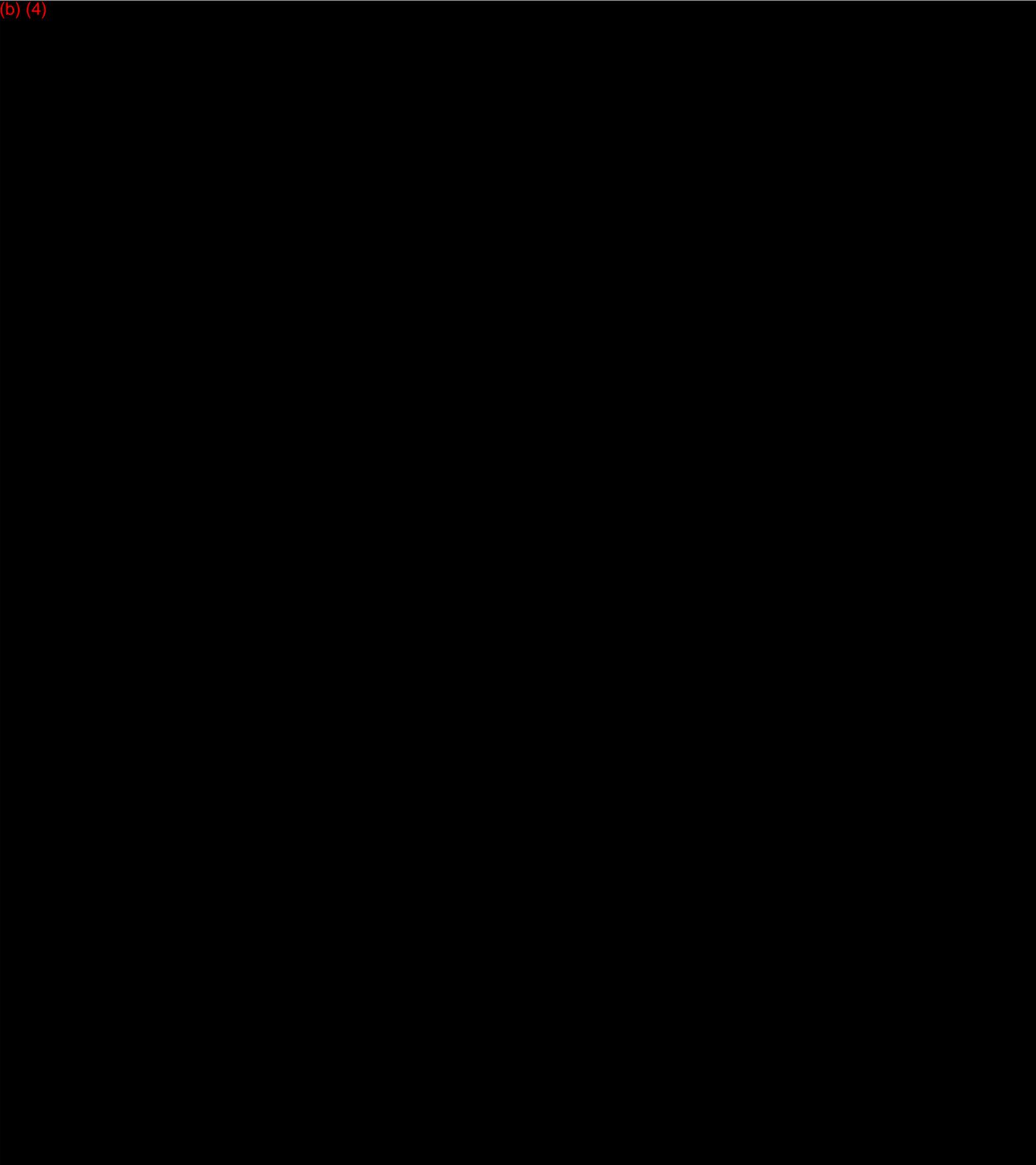
I, Alex Lucio, believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

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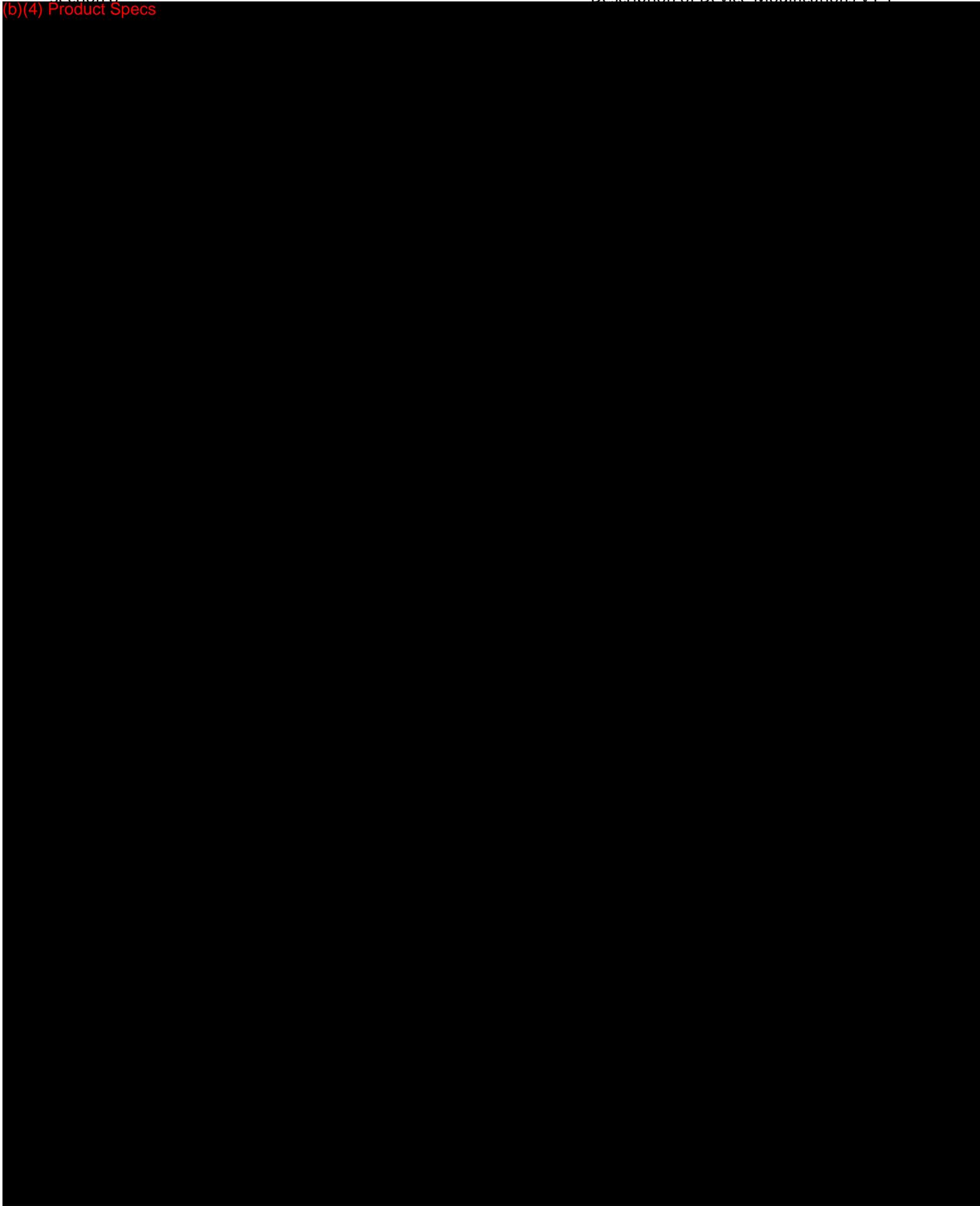
Alex Lucio
Vice President
3B Medical, Inc.
21301 Highway 27 N
Lakes Wales, FL 33859

Description of Device Modifications

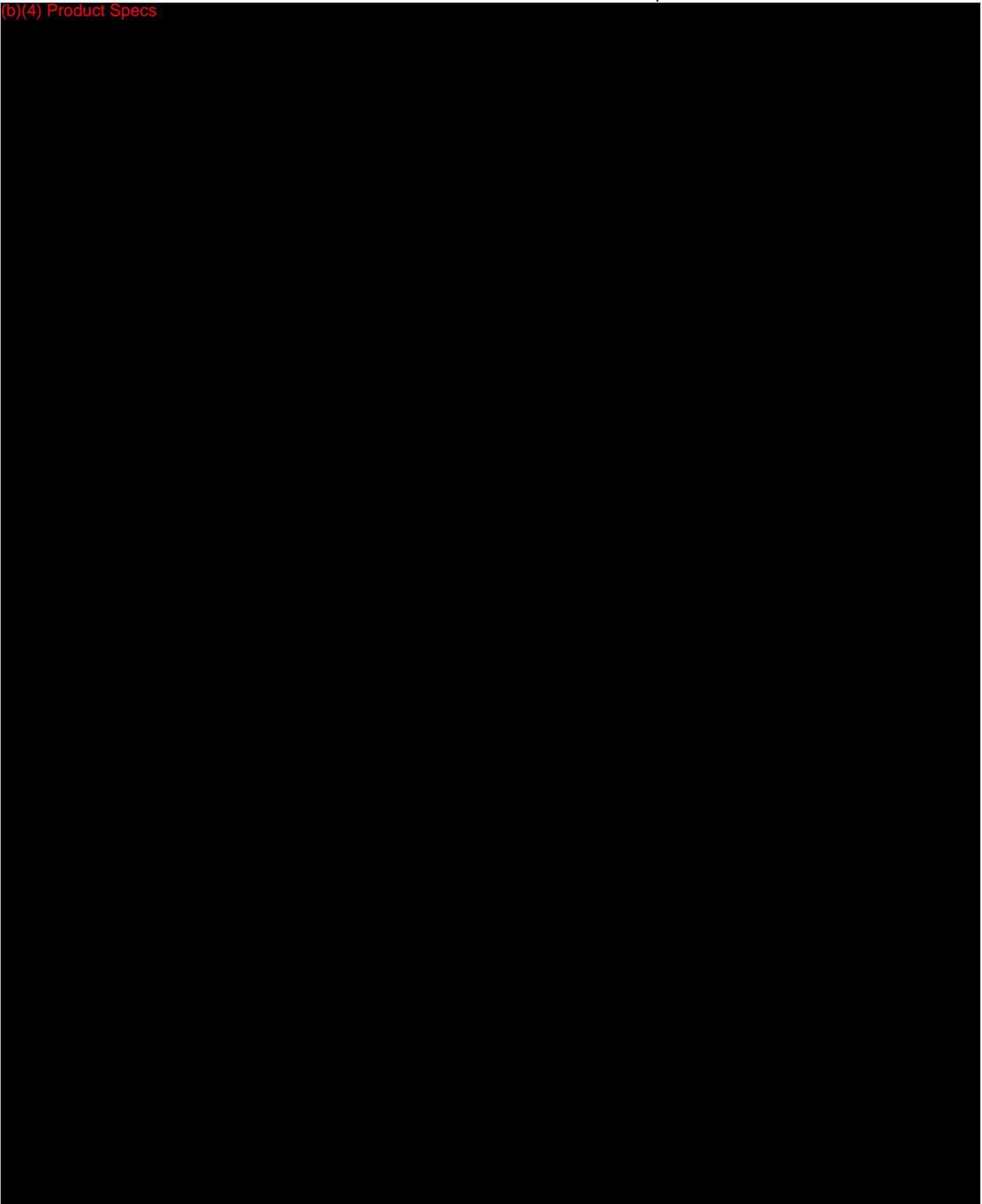
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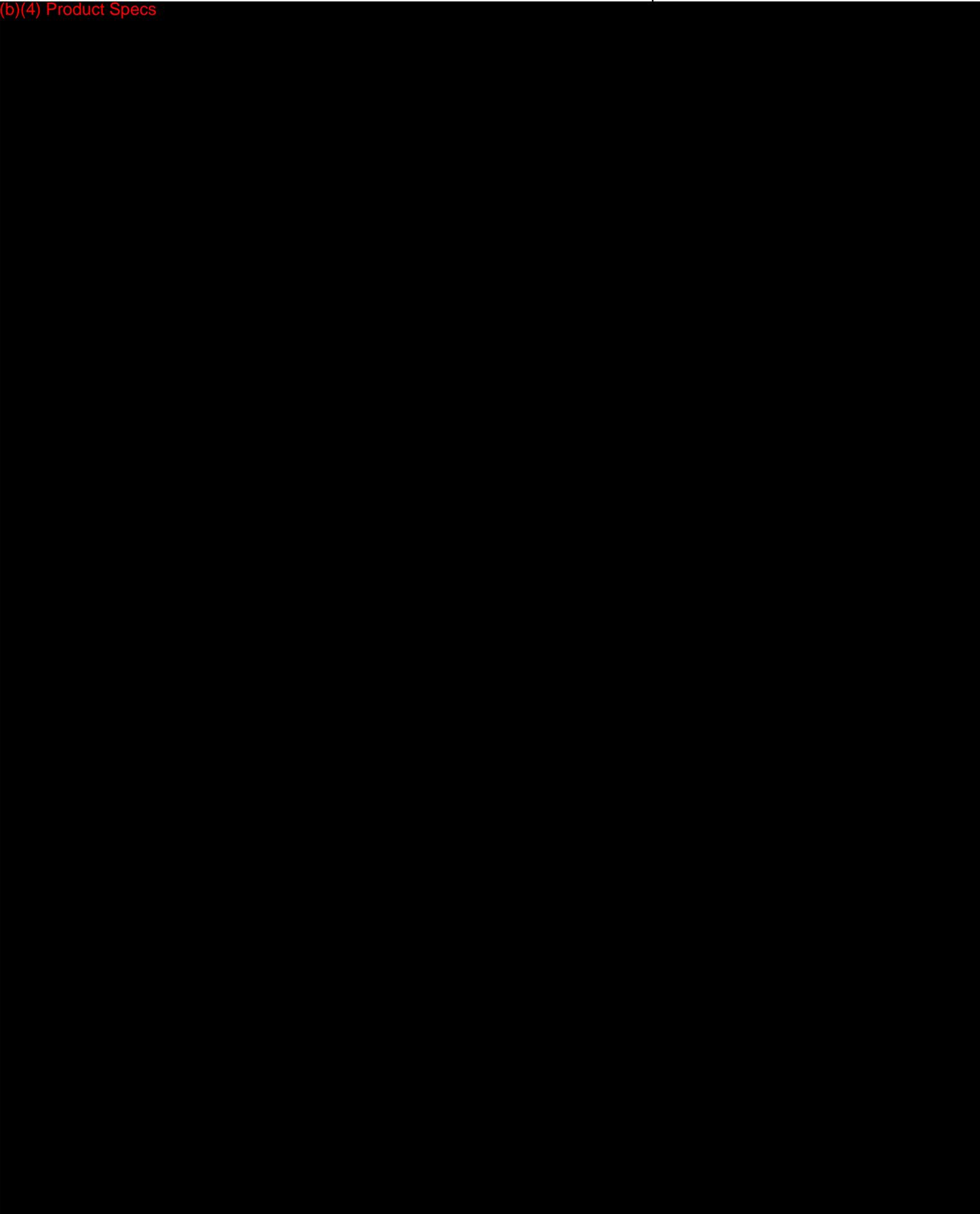
(b)(4) Product Specs



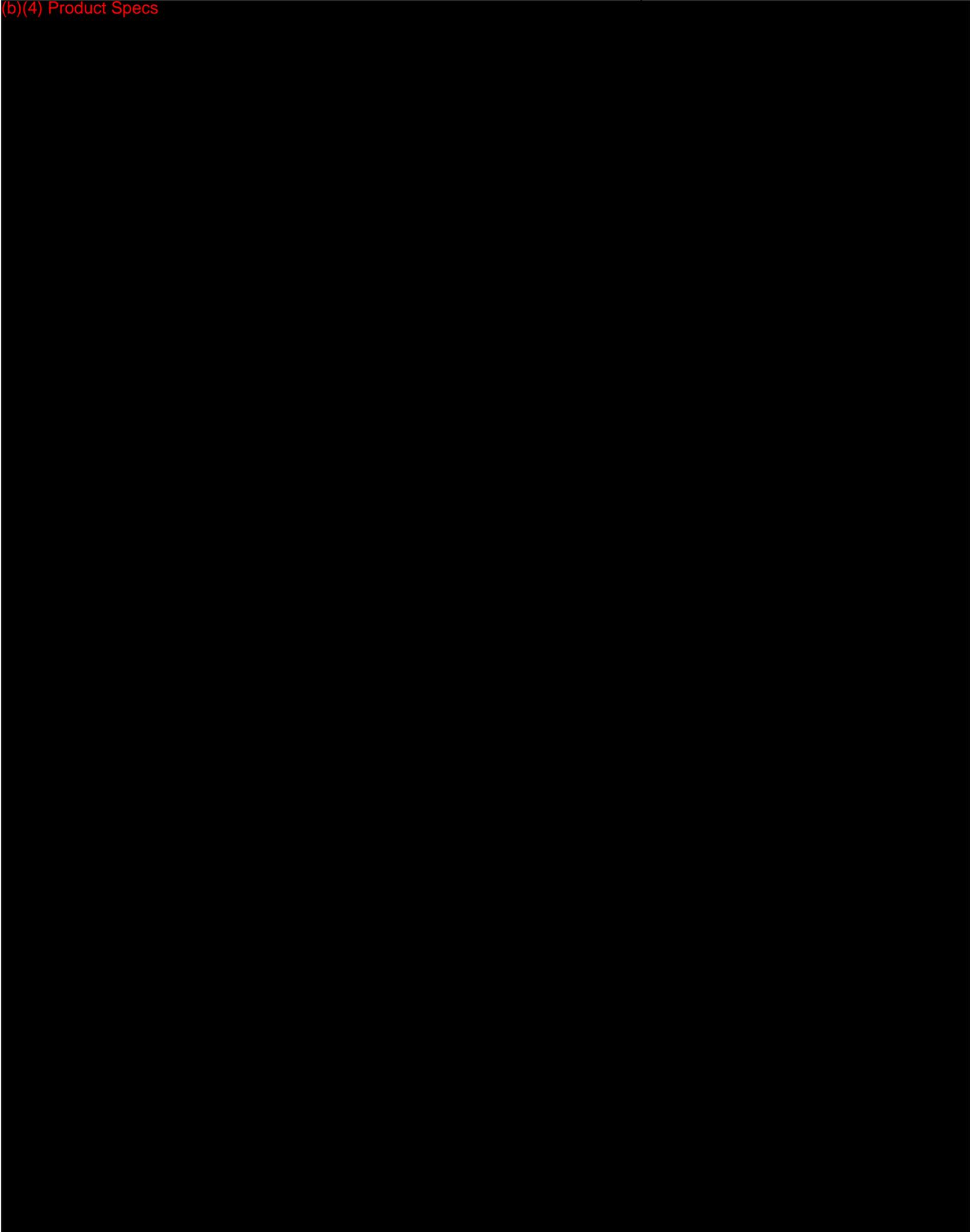
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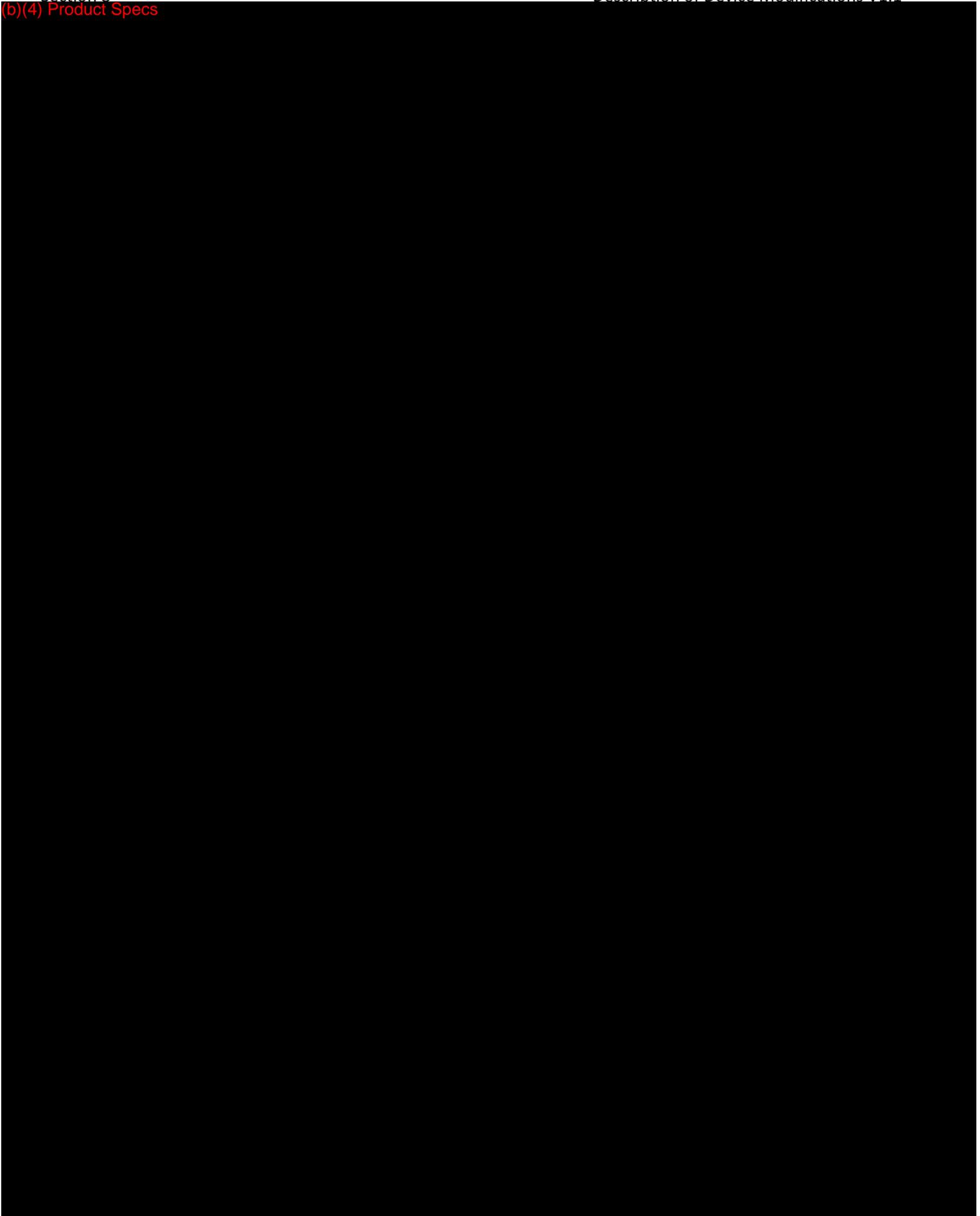
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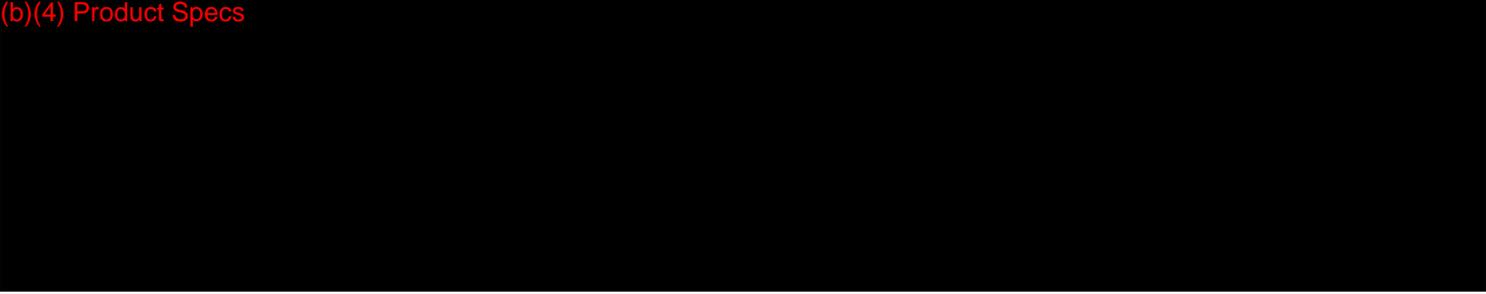
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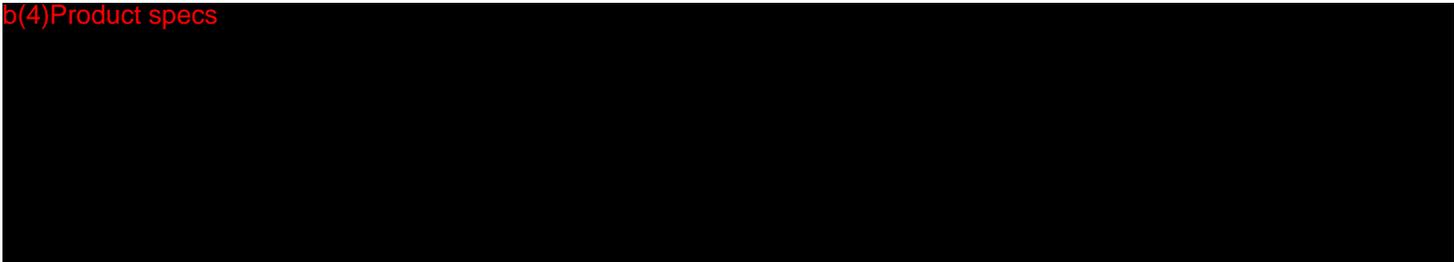
(b)(4) Product Specs



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(b)(4) Product specs



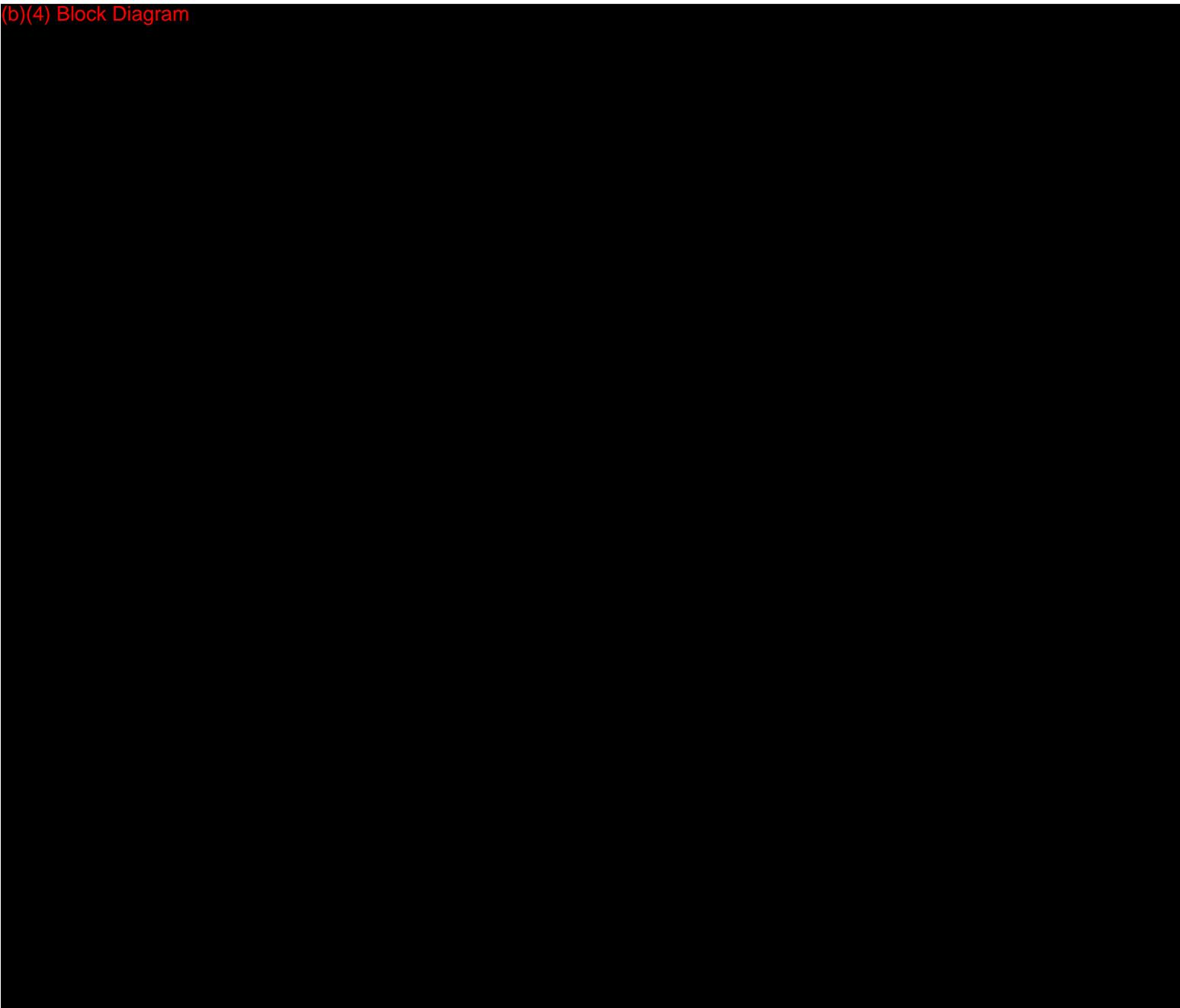
Section 9: Device Description

1. Intended use

The 3B and BMC RESmart GII CPAP and Auto-CPAP devices (also sold as the 3B Luna CPAP and Auto-CPAP devices) are intended to deliver positive pressure for the treatment of Obstructive Sleep Apnea. The optional integrated humidifier is indicated for the humidification and warming of air from the flow generator device. These devices are intended for use by prescription in the home or hospital/institutional environment on adult patients.

2. Construction of CPAP/Auto CPAP system

(b)(4) Block Diagram

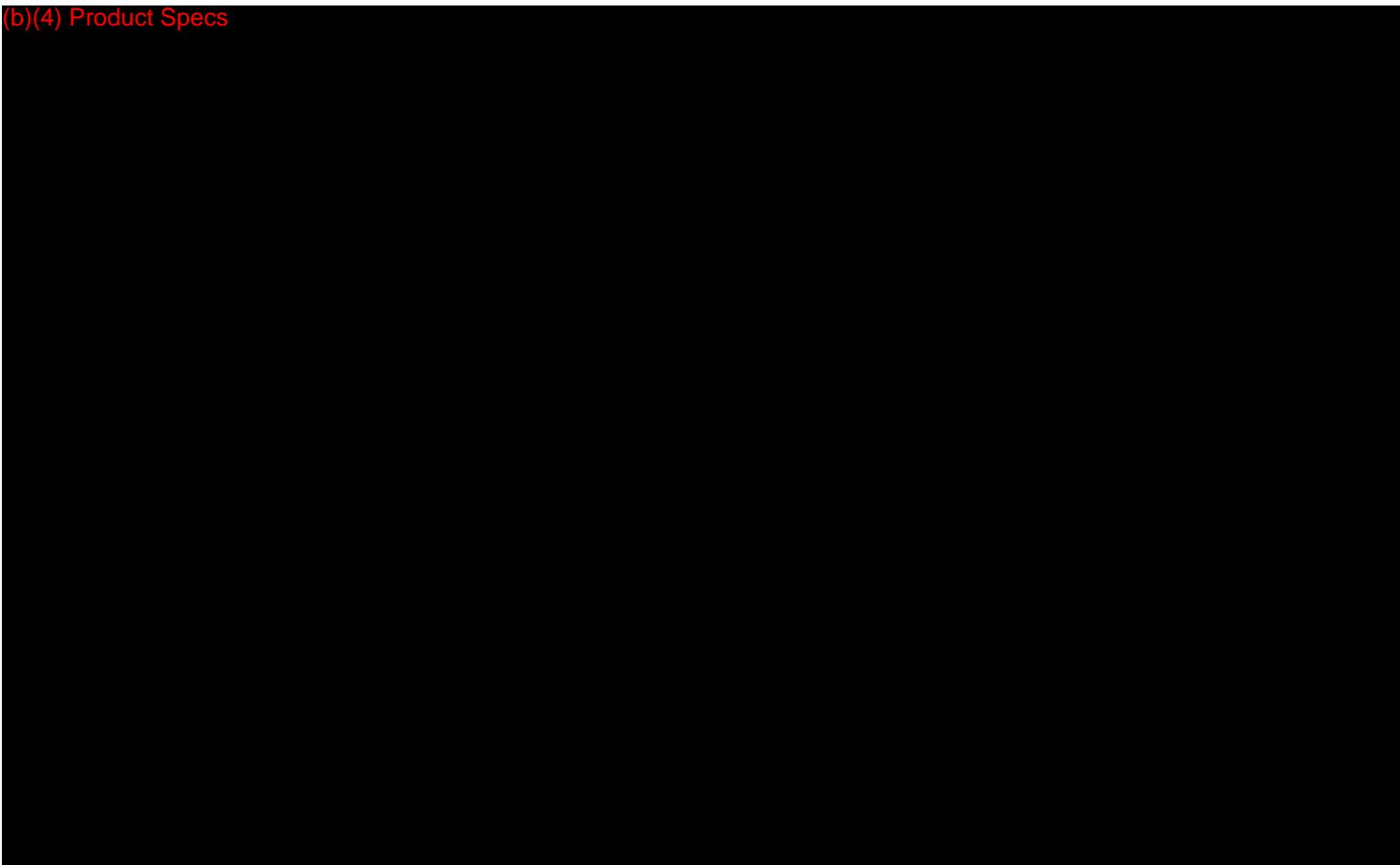


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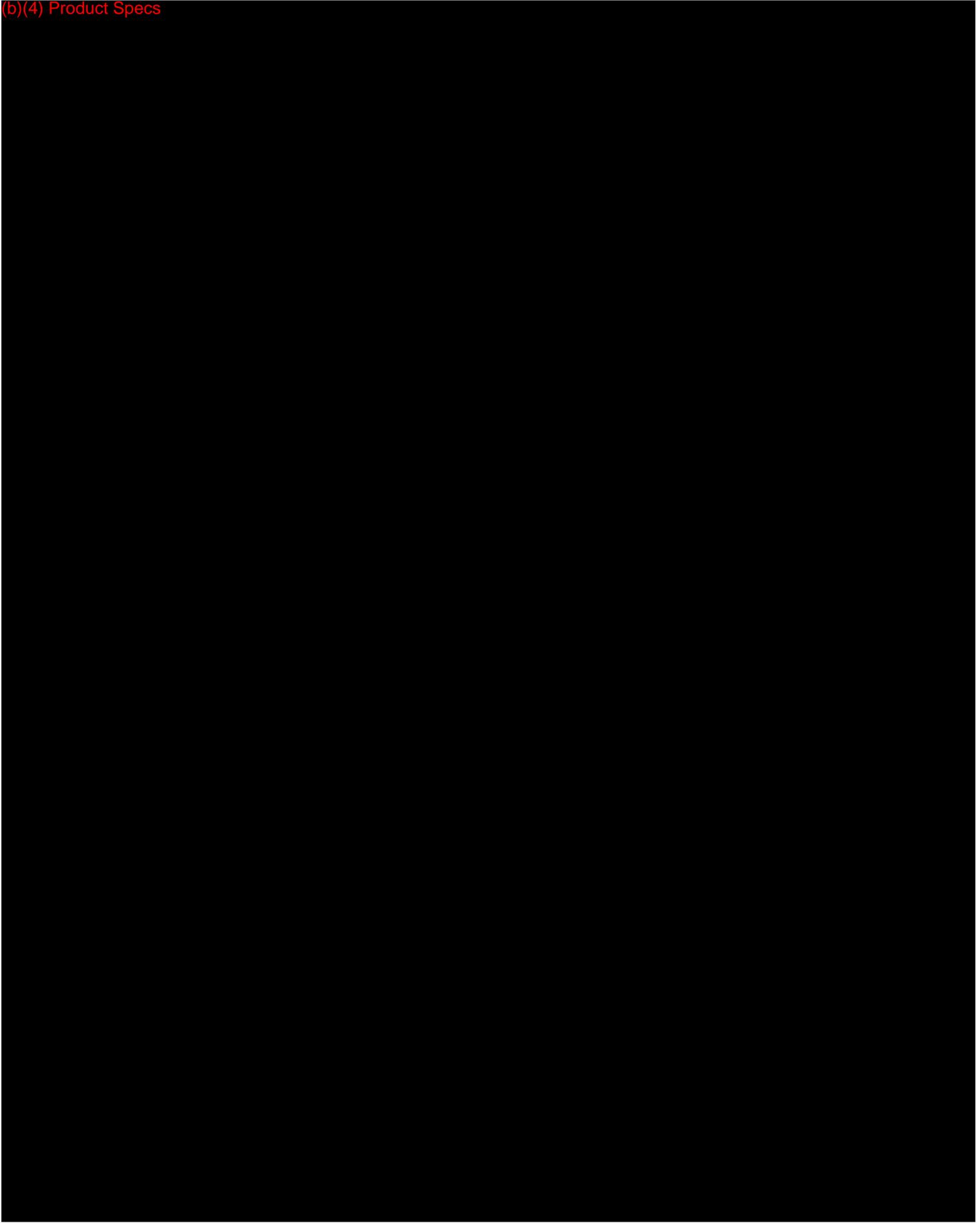


3. Device Operation

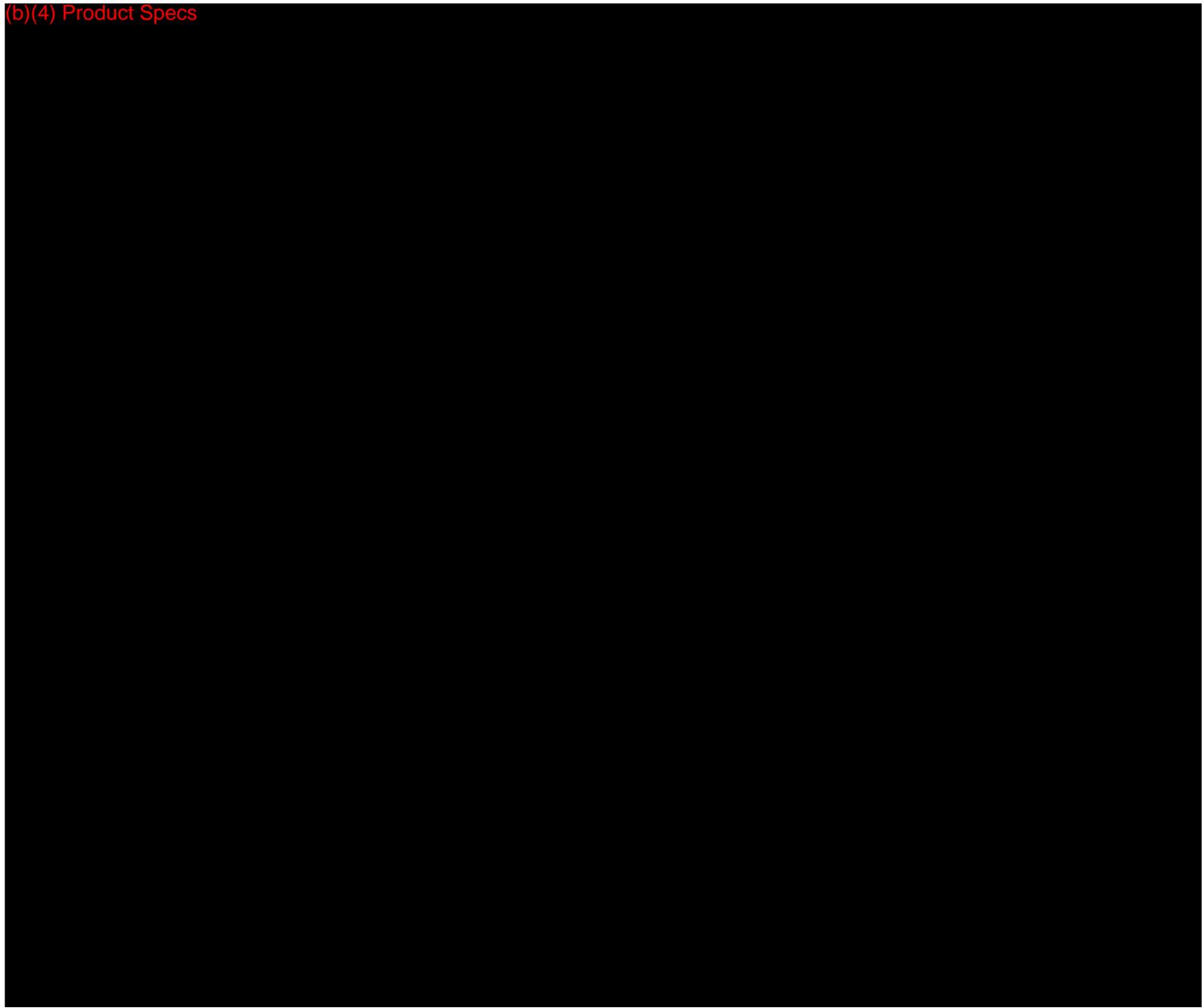
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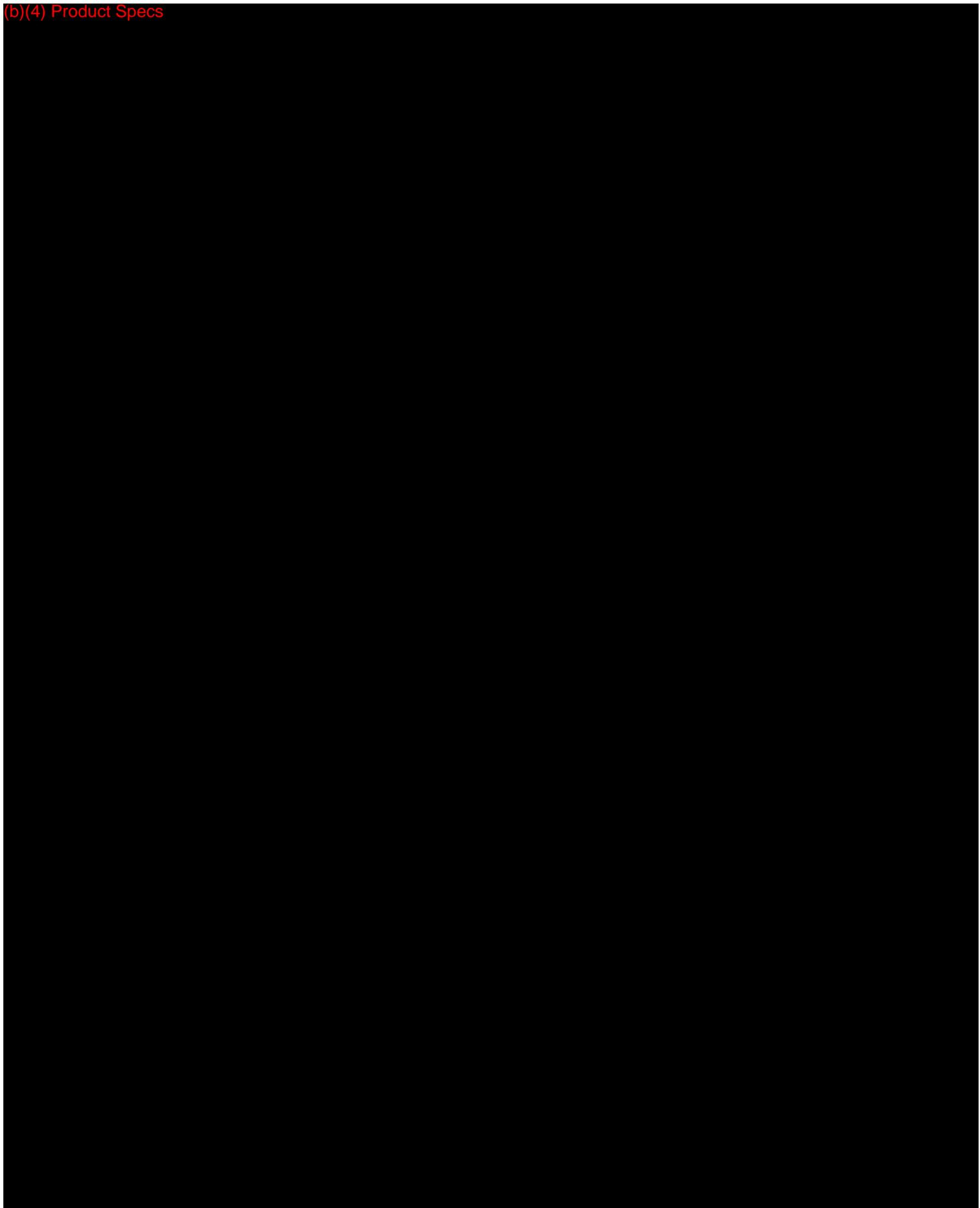
(b)(4) Product Specs



(b)(4) Product Specs



(b)(4) Product Specs

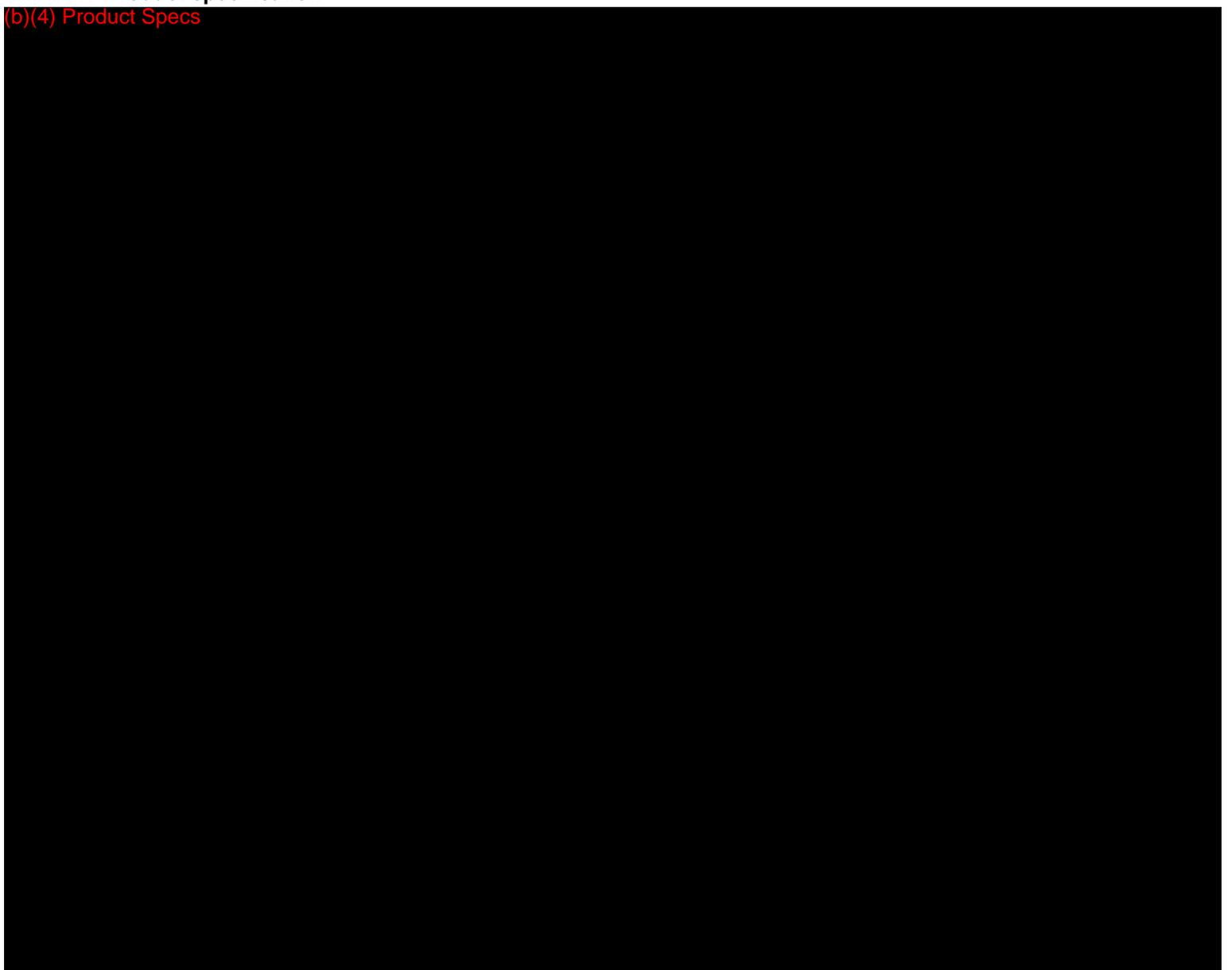


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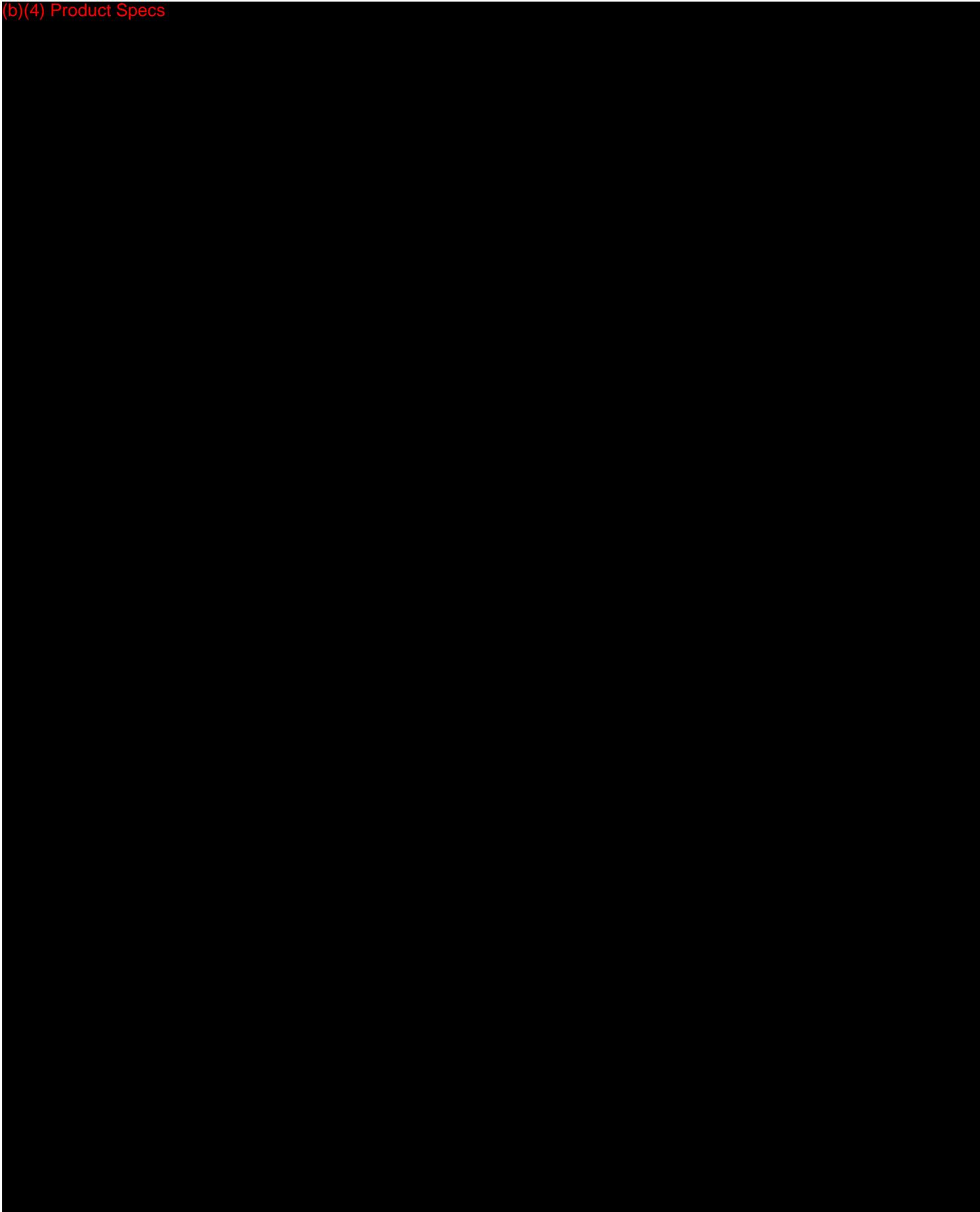


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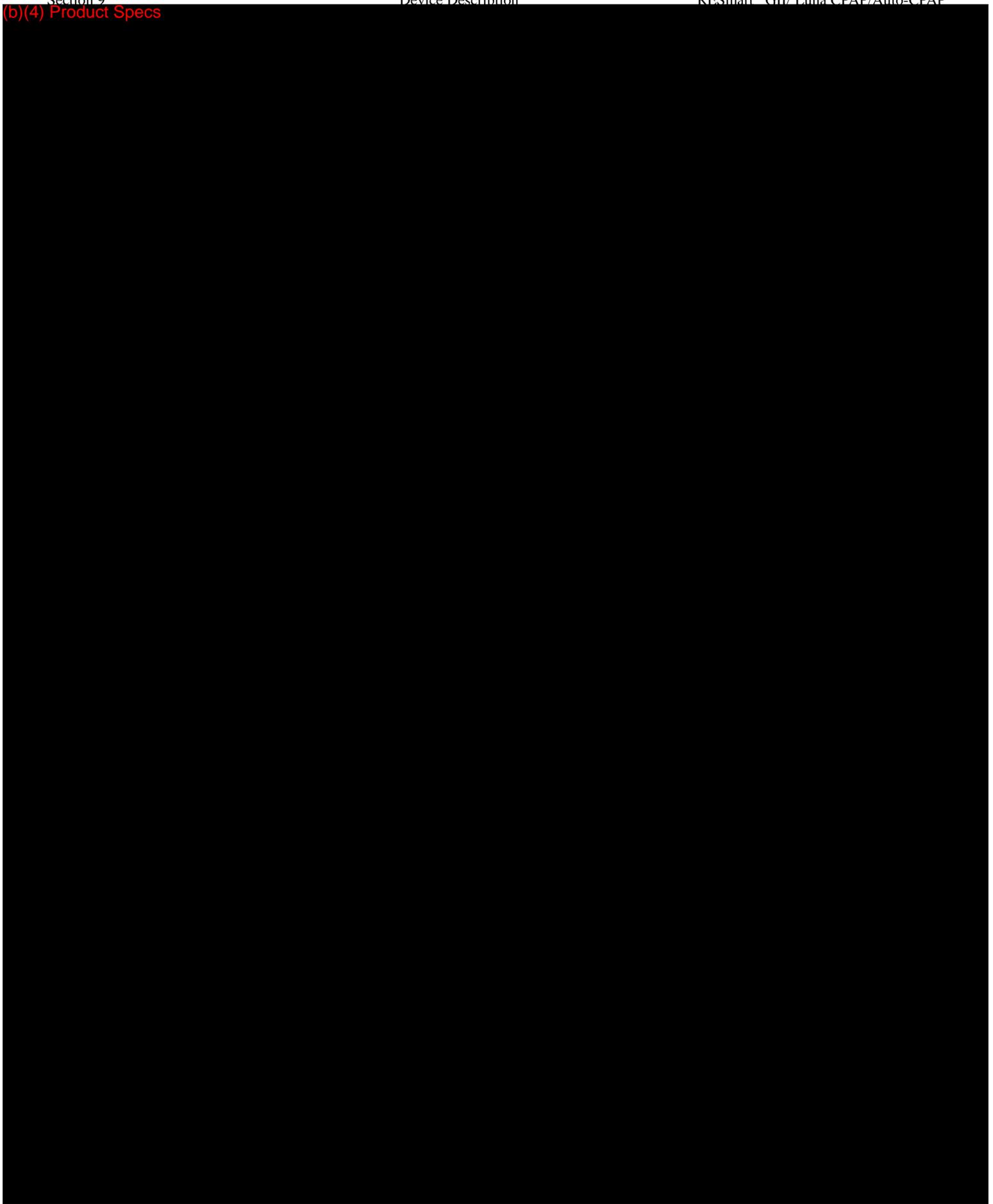
(b)(4) Product Specs



(b)(4) Product Specs



(b)(4) Product Specs



(b)(4) Product Specs



12. Photo of the Product



CPAP/Auto CPAP System without the Humidifier (Display is 2.4inch)



Auto CPAP System without the Humidifier (Display is 3.5inch)



Humidifier

13. Accessories

The humidifier is an integrated unit, that snaps into place on the CPAP/APAP, but is sold separately.

The CPAP and Auto CPAP are not sold with mask, tubing or bacterial filters. These accessories may be purchased separately, and the product line is designed to accommodate standard CPAP tubing (22mm) for easy interconnectibility of masks and air tubing.

SUBSTANTIAL EQUIVALENCE

The proposed RESmart GII CPAP and Auto-CPAP Systems (also sold as the Luna CPAP and Auto-CPAP System), is a second generation redesign of the predicate device, the RESmart (K132967). The purpose of the redesign was to make the device more aesthetically appealing and easier to use. To this end, the redesign effort included the addition of a larger color LCD with a graphical user interface and a cosmetic redesign of the enclosure. The second generation proposed device (GII) remains substantially equivalent to the predicate (K132967) in that both the proposed and predicate devices share the same intended use, operating principle, technology and manufacturing process.

I. Indication for Use

The predicate and proposed devices' indications for use are identical and are as follows:

The 3B and BMC RESmart GII CPAP and Auto-CPAP Systems are intended to deliver positive pressure for the treatment of Obstructive Sleep Apnea. The optional integrated humidifier is indicated for the humidification and warming of air from the flow generator device. These devices are intended for single patient use by prescription in the home or hospital/institutional environment on adult patients.

Both systems are for prescription use only.

II. Operation of the Device

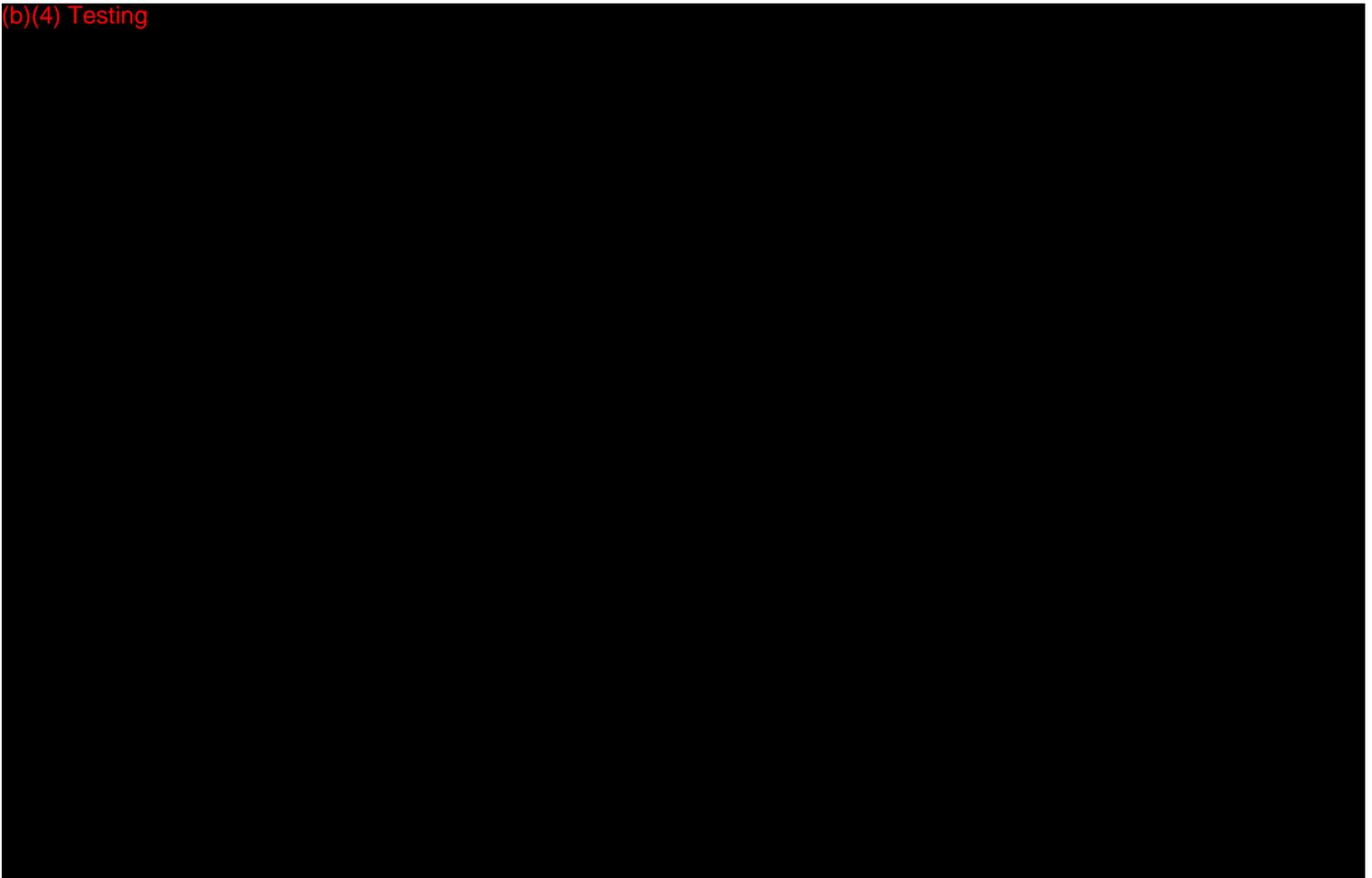
The RESmart GII System treats sleep apnea by delivering positive pressure to the patient's airway at a set pressure controlled by the device's motor speed. A pressure sensor and a flow sensor detect two key signals: pressure and flow rate. This creates a closed-loop feedback pressure control system that allows real time monitoring of respiration events. In response to these feedback signals, the device adjusts motor speed to deliver the prescribed pressure. In responding to pressure fluctuations occurring when

the patient breathes, the motor may operate at a constant speed, accelerate, or decelerate to respond on a breath-by-breath basis to variations in air pressure in the air circuit. The comprehensive performance of the motor, drive system and air circuit is measured through static pressure stability and dynamic pressure stability. The internal control mechanism, including blower fan, controller board, processor board and power supply of both the predicate and proposed device remain unchanged. Bench testing confirms that performance of both the predicate and proposed devices are substantially equivalent (See Appendix N, Comparative Performance Bench Testing of Predicate and Proposed Device).

There are no changes involving the software logic or algorithm of the proposed device, so the clinical efficacy of the both predicate and proposed devices remain unchanged.

III. Biocompatibility

(b)(4) Testing

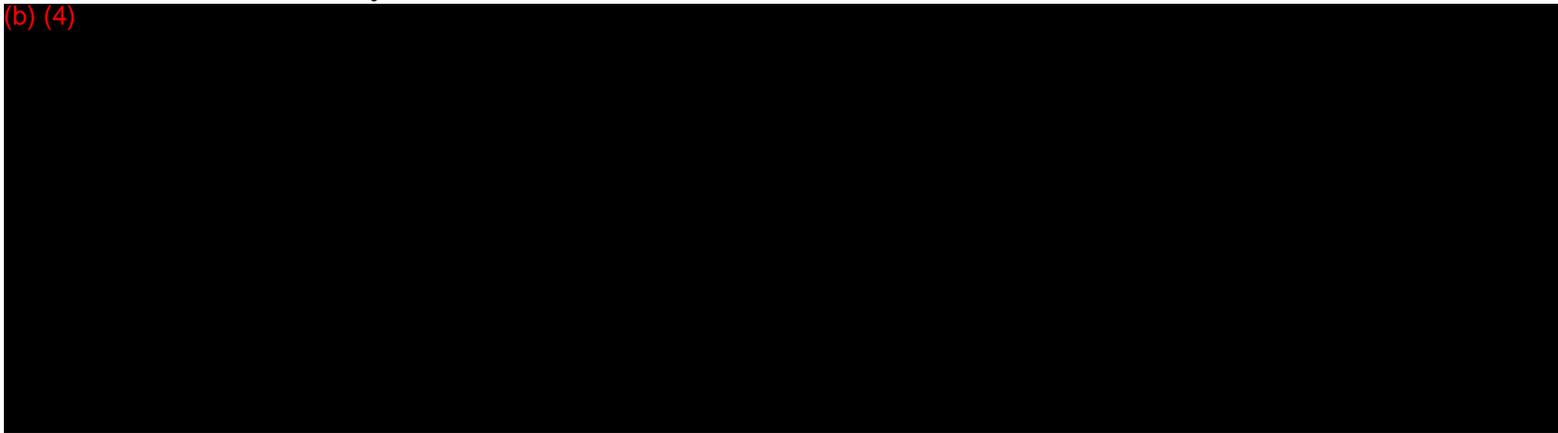


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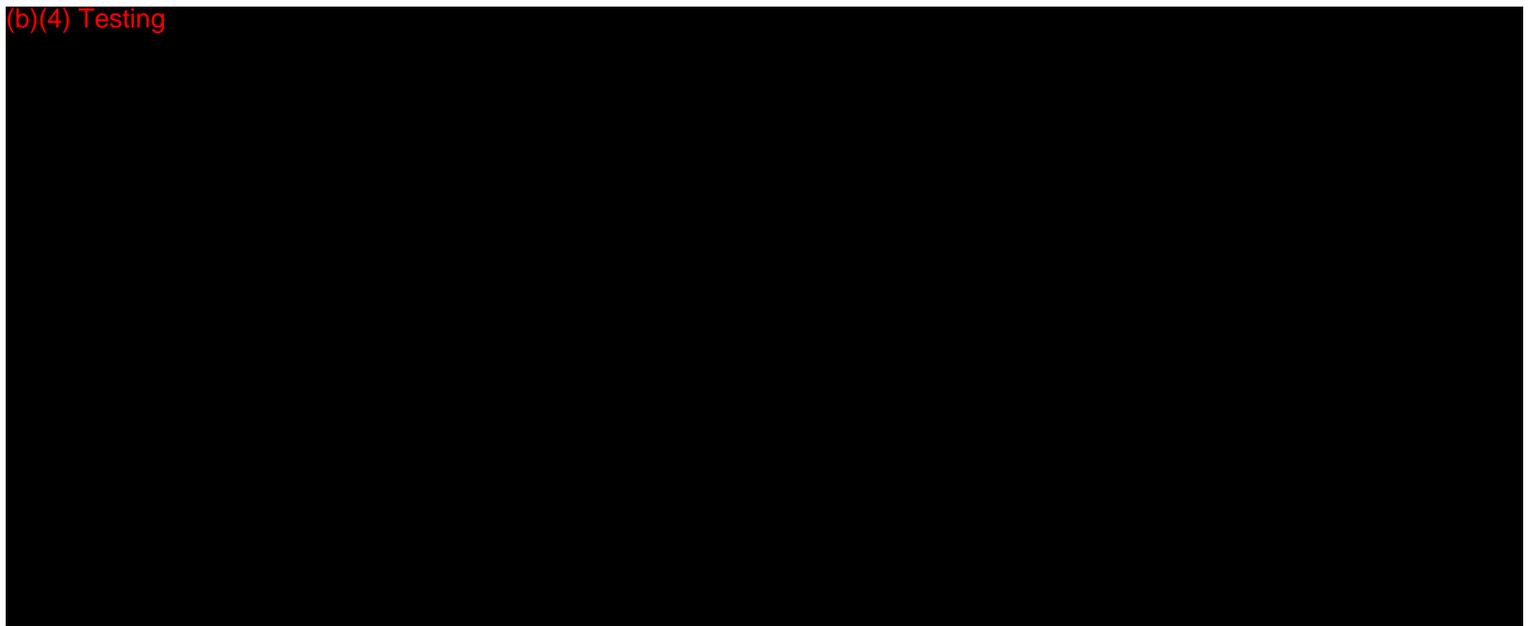
IV. Electrical System

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V. Air Quality Testing

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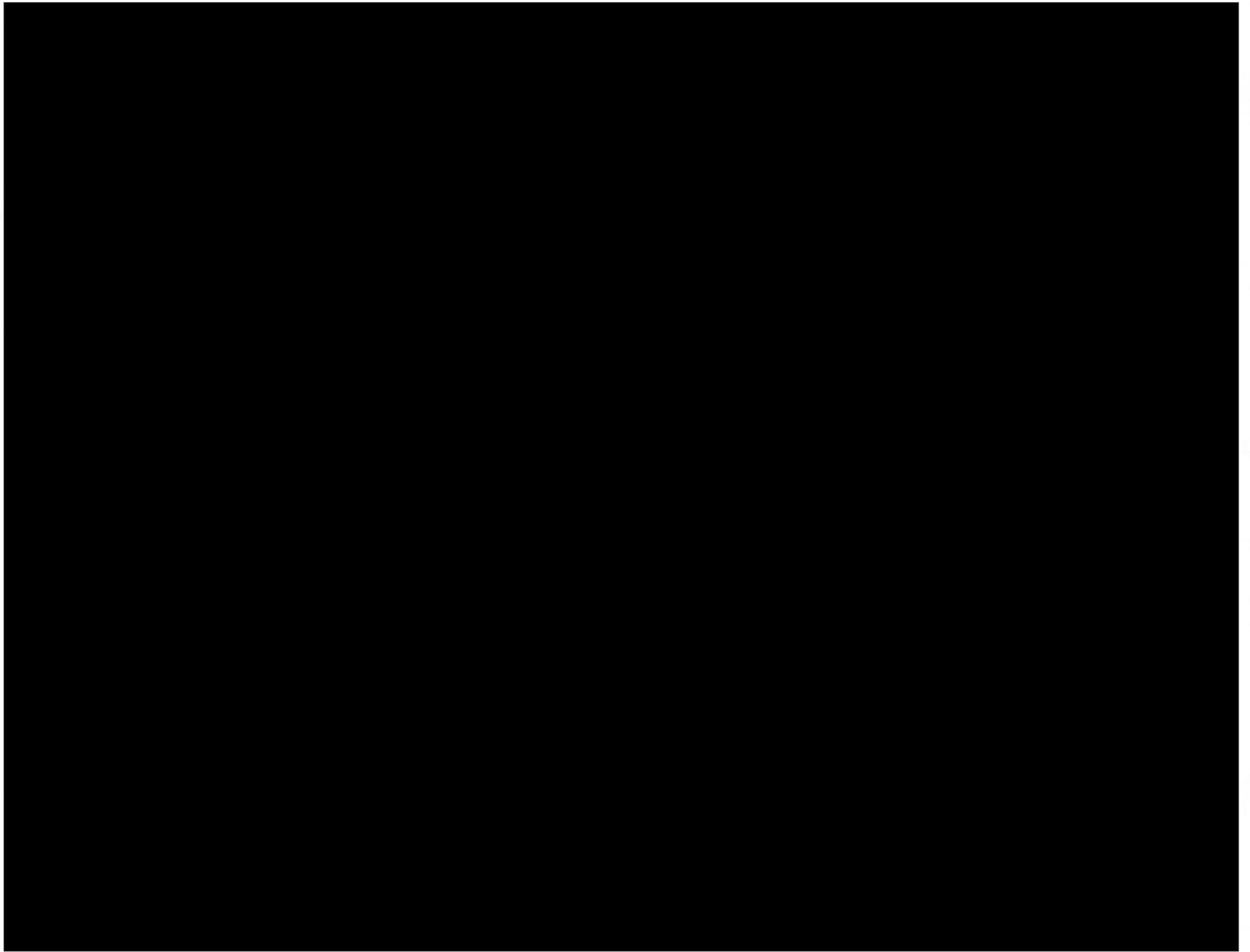
VI. Changes to Labeling

(b)(4) Testing



CONCLUSION

Based on the foregoing, the proposed RESmart GII CPAP and Auto-CPAP System remains substantially equivalent to the predicate RESmart CPAP and Auto-CPAP System K132967 in that the systems share the same intended use, operating principle, technology, and manufacturing process.



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Summary of Risk Management and Risk Analysis

1 Introduction

1.1 Project overview

This document summarizes the risk management plan of the RESmart GII CPAP and Auto-CPAP System, hereinafter referred to as GII. The GII device is so named because it is the second generation redesign of the RESmart CPAP and Auto-CPAP device. The scope of the redesign consists of a more modern enclosure and the addition of a larger color LCD display and a menu driven GUI.

1.2 References

1.2.1 Project References

Document Identifier	Document Title
YF-nP2-5-67	Risk Management Report
YF-nP2-5-18	Human Factors Report

1.2.2 Standard and Regulatory References

ISO 14971, IEC 6060, MDD93/42/ECC, and MDD2007/47EC

2. Documentation

The risk management report of the RESmart GII CPAP and Auto-CPAP System is found at Appendix R (Doc No. YF-nP2-5-67).

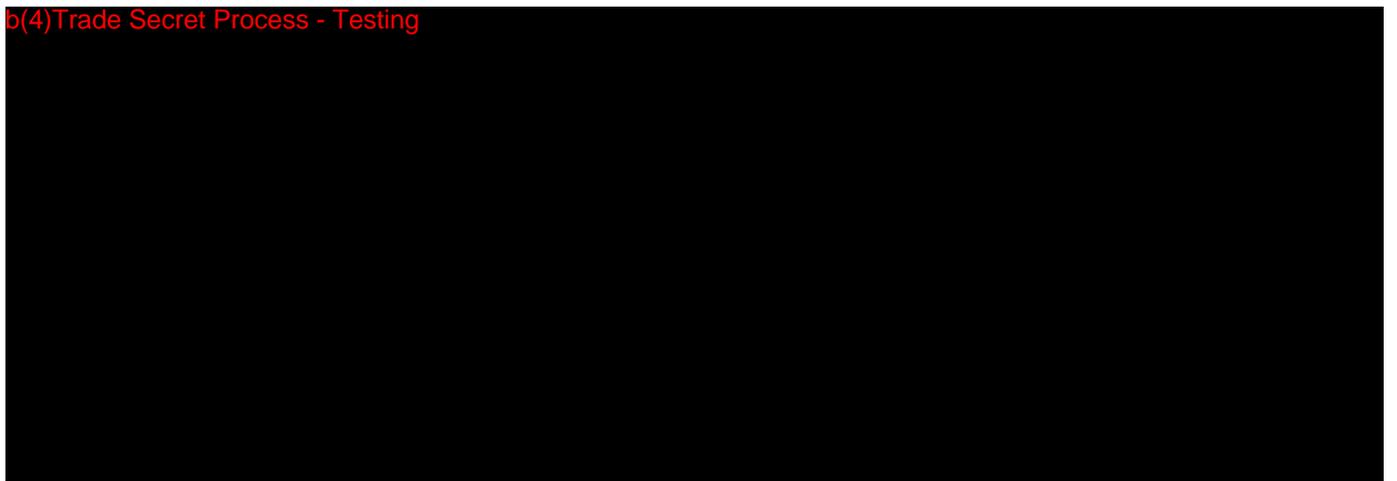
Section 13: BIOCOMPATIBILITY OF MATERIALS

b(4)Trade Secret Process - Testing

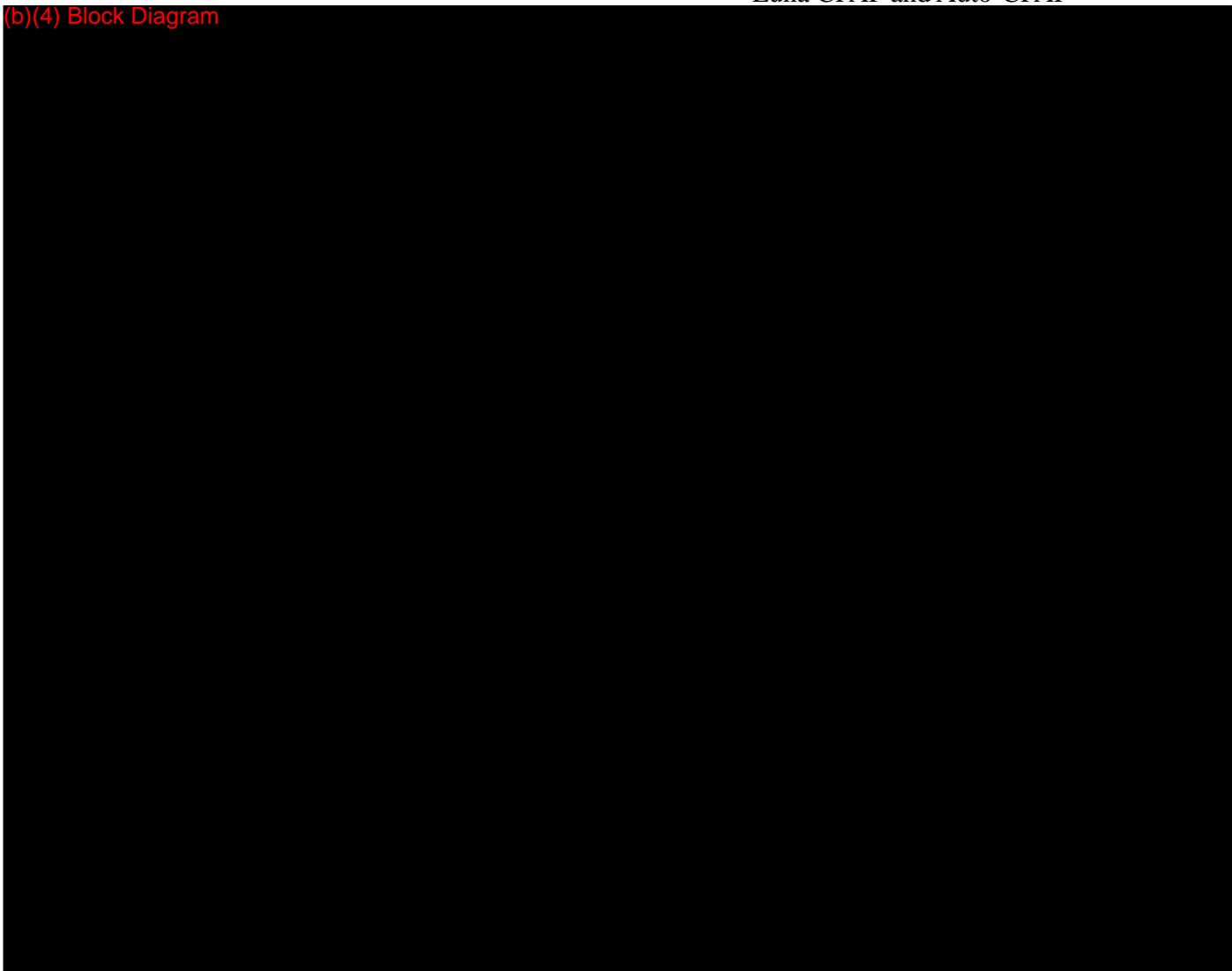


Materials in contact with the air path of RESmart© BPAP and RESmart© Auto

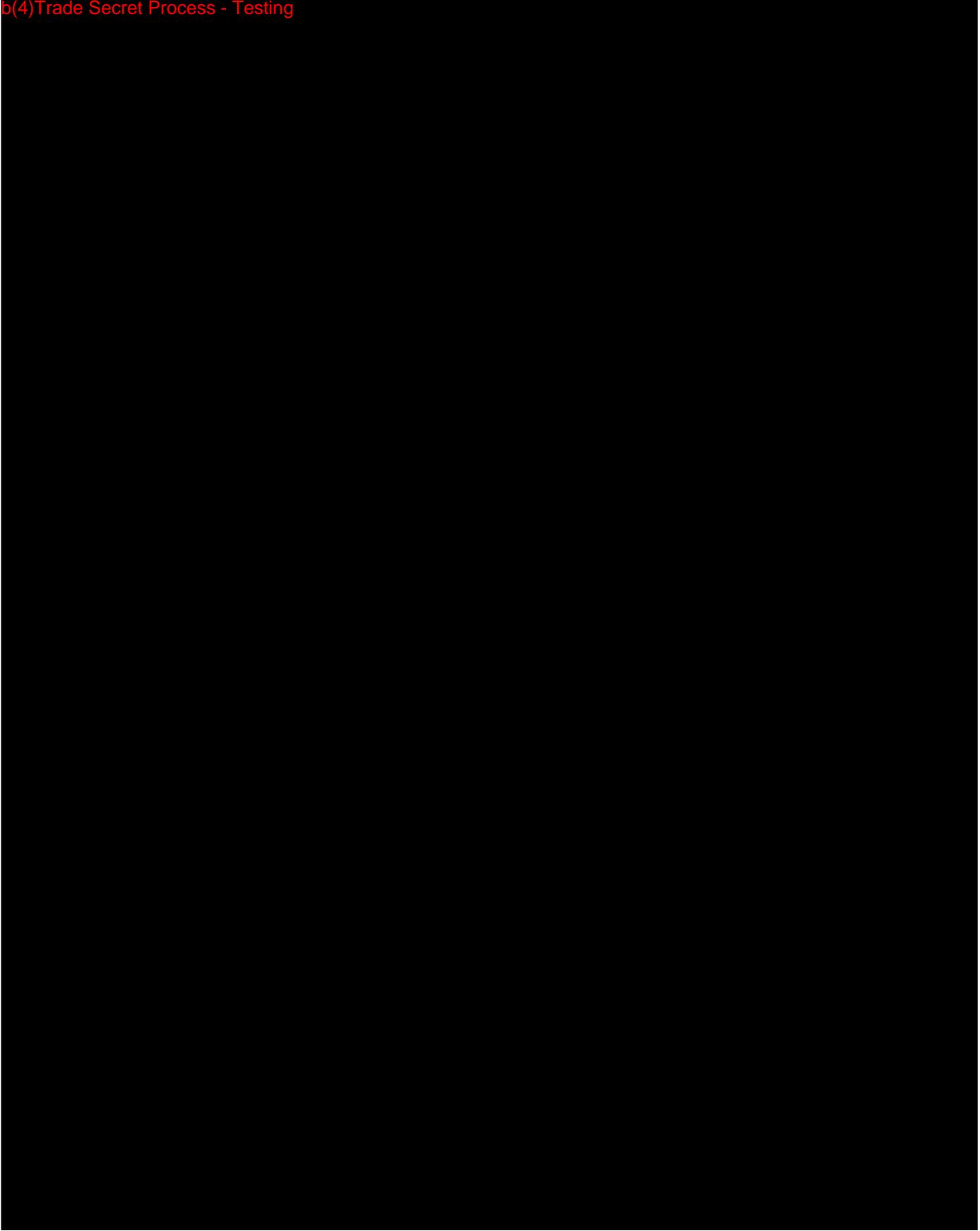
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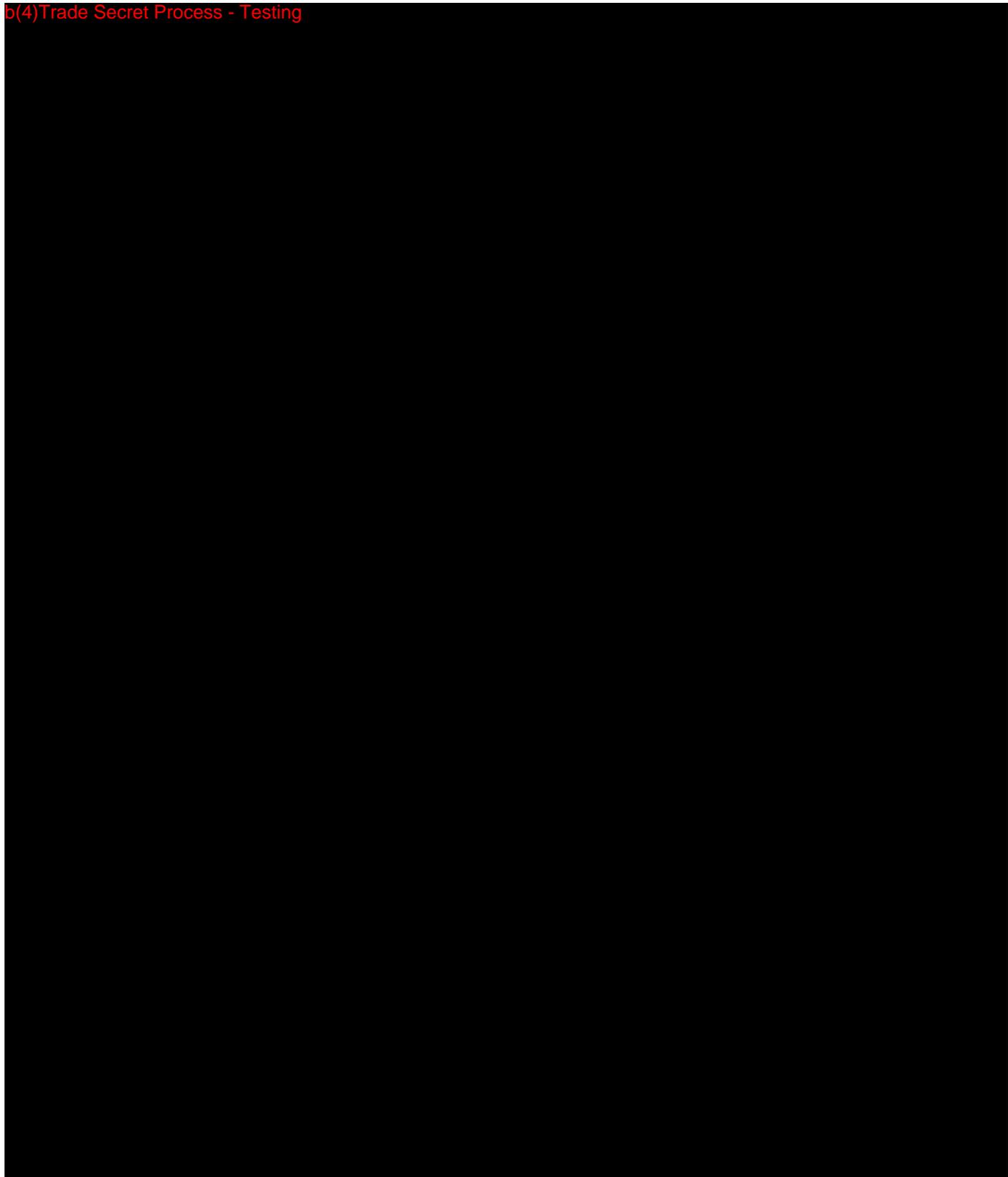
(b)(4) Block Diagram



b(4)Trade Secret Process - Testing



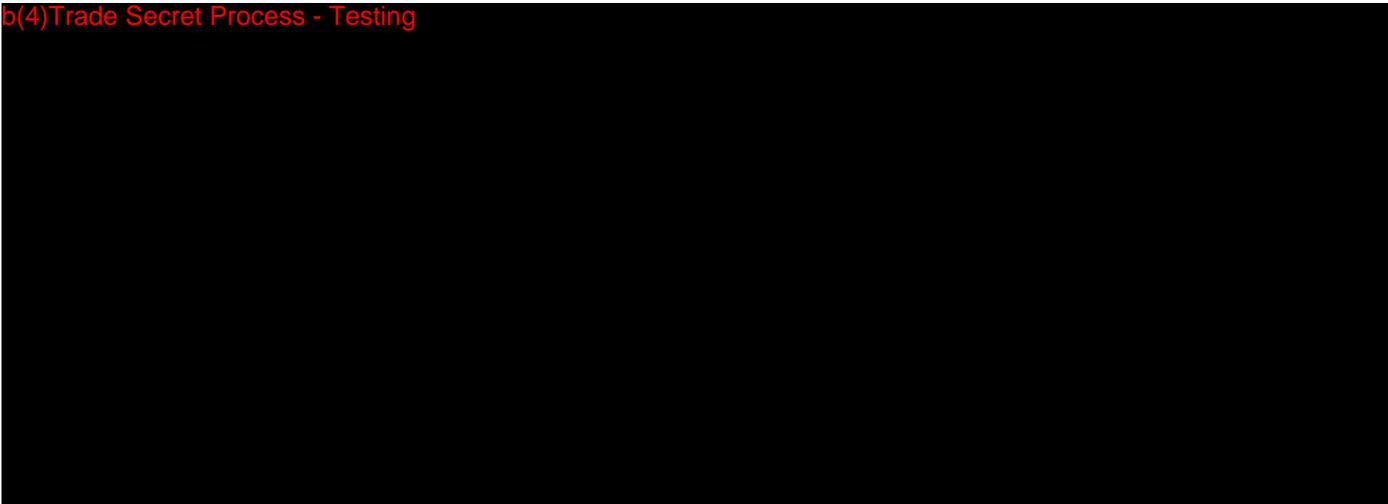
b(4)Trade Secret Process - Testing



b(4) Trade Secret Process - Testing



b(4)Trade Secret Process - Testing



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D. 2.2 Reliability Test Report for E-20A & H60	EASZG02180005-1
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CONFIDENTIAL: The contents of this appendix, inclusive of Appendix A through Z, is deemed confidential in its entirety and not subject to public disclosure.

b(4)Trade Secret Process - Testing

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3B™

E-20A System

User Manual



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1. Symbols

1.1 Control Buttons

-  Ramp Button
-  Mute Button
-  Knob

1.2 Device Symbols

-  Operating Instructions
-  Type BF Applied Part (mask)
-  Class II (Double Insulated)
-  AC Power
-  DC Power
- IP22** ≥ 12.5 mm Diameter, Dripping (15° tilted)
-  Hot Surface
-  Serial Number of the Product
-  Manufacturer
-  Authorized Representative in the European Community
-  European CE Declaration of Conformity
-  SD Card
-  Water Filling Prohibited Here
-  Water Inlet
-  Directional Indicator for Removing the Water Inlet Cap
-  Directional Indicator for Screwing the Water Inlet Cap

2. Warning, Caution and Important Tip

WARNING!

Indicate the possibility of injury to the user or operator.

CAUTION!

Indicate the possibility of damage to the device.

IMPORTANT TIP!

Place emphasis on an operating characteristic.

Warnings, Cautions, and Important Tips appear throughout this manual as they apply.

3. Intended Use

The E-20A system is a CPAP (Continuous Positive Airway Pressure) device designed for the treatment of adult Obstructive Sleep Apnea (OSA) only.

The device is to be used only on the instruction of a licensed health care professional. Your home care provider will make the correct pressure settings according to your health care professional's prescription.

Several accessories are available to make your OSA treatment with this device as convenient and comfortable as possible. To ensure that you receive the safe, effective therapy prescribed for you, use only BMC accessories.

WARNINGS!

- This device is intended for adult use only.
- This device is not intended for life support.
- The instructions in this manual are not intended to supersede established medical protocols.

CAUTION!

- This device is restricted to sale by or on the order of a physician.
- The device is intended for use by operators trained or experienced in similar equipment. • The patient is an intended operator.
- Cleaning and disinfection can be performed by the patient.

IMPORTANT!

- Read and understand the entire user manual before operating this system. If you have any questions concerning the use of this system, contact your home care provider or health care professional.

4. Contraindications

Studies have shown that the following pre-existing conditions may contraindicate the use of positive airway pressure therapy for some patients:

Absolute Contraindications: pneumothorax, mediastinal emphysema; cerebrospinal fluid leak, traumatic brain injury, or pneumocephalus; shock caused by a variety of conditions before treatment; active epistaxis; upper gastrointestinal bleeding before treatment; coma or impaired consciousness making the use of mask during therapy impossible; giant vocal fold polyp, etc.

Relative Contraindications: severe coronary heart disease complicated with left ventricular failure, acute otitis media, excessive respiratory secretions and weak cough, weak spontaneous breathing, nasal or oral tracheal intubation and tracheotomy, severe nasal congestion caused by a variety of conditions, lung bullae, and allergies to breathing masks, etc.

The following side effects may occur during treatment:

- Dryness of the mouth, nose and throat
- Abdominal bloating
- Ear or sinus discomfort
- Eye irritation
- Skin irritation due to the use of a mask
- Chest discomfort

IMPORTANT!

- An irregular sleep schedule, alcohol consumption, obesity, sleeping pills, or sedatives may aggravate your symptoms.

CAUTION!

- Contact your health care professional if symptoms of sleep apnea recur. Contact your health care professional if you have any questions concerning your therapy.

5. Specifications

Device Size

Dimensions: 170 × 196 × 118 mm, or 290 × 196 × 134 mm (with the humidifier)

Weight: 1.5 kg, or 2.5 kg (with the humidifier)

Product Use, Transport and Storage

	Operation	Transport and Storage
Temperature:	5 to 35°C (41°F to 95°F)	-20 to 55°C (-4°F to 131°F)
Humidity:	15% to 93% Non-condensing	15% to 93% Non-condensing
Atmospheric Pressure:	760-1060 hPa	760-1060 hPa

Mode of Operation

Continuous

Work Mode

CPAP, AUTO

SD Card

With a capacity ≥ 2 G, the SD card can record patient data and fault information. Furthermore, the language pack stored on the SD card enables you to change the language of the device.

AC Power Consumption

100–240 V AC, 50/60 Hz, 2.0 A max

Type of Protection Against Electric Shock

Class II Equipment

Degree of Protection Against Electric Shock

Type BF Applied Part

Degree of Protection Against Ingress of Water

IP22

Pressure Range

4 to 20 hPa (in 0.5 hPa increments), ≤ 30 hPa under single fault conditions.

Pressure Display Accuracy

$\pm(0.5 \text{ hPa} + 4\%)$

Pressure Stability

4 to 20 hPa (± 1 hPa)

Ramp

The ramp time ranges from 0 to 60 minutes

Sound Pressure Level

<30 dB, when the device is working at the pressure of 10 hPa.

Sound Power Level

<38 dB, when the device is working at the pressure of 10 hPa.

Maximum Flow

Test Pressure (hPa)	4	9	15	20
Average Flow at the Patient Connection Port (l/min)	80	92	91	96

Tube

Length: 6 ft. (1.83 m)

The Form and the Dimensions of the Patient Connection Port

The 22 mm conical air outlet complies with ISO 5356-1

6. Available Therapies

The device delivers the following therapies:

CPAP- Delivers Continuous Positive Airway Pressure; CPAP maintains a constant level of pressure throughout the breathing cycle. If your health care professional has prescribed ramp for you, you can press **the Ramp Button**  to reduce the pressure and then gradually increase the pressure to the therapeutic pressure setting so that you can fall asleep more comfortably.

Auto- Delivers CPAP therapy and provides an air pressure no less than the prescribed one based on the patient's needs.

7. Glossary

Apnea

A condition marked by the cessation of spontaneous breathing.

Auto-CPAP

Adjust CPAP pressure automatically to improve patient comfort based on monitoring of apnea and snoring events.

Auto Off

When this feature is enabled, the device automatically discontinues therapy whenever the mask is removed.

Auto On

When this feature is enabled, the device automatically initiates therapy when you breathe into the mask.

CPAP

Continuous Positive Airway Pressure

iCode

A feature that is intended to give access to compliance and therapy management information. The "iCode" consists of six separate codes displayed in the Patient Menu. iCode I displays sequences of characters, and iCode II displays two-dimensional codes .

LPM

Liters Per Minute

OSA

Obstructive Sleep Apnea

Patient Menu

The display mode in which you can change patient-adjustable device settings, such as the starting pressure for the Ramp feature.

Ramp

A feature that may increase patient comfort when therapy is started. It can reduce pressure and then gradually increase the pressure to the prescription setting so the patient can fall asleep more comfortably.

RESlex

A therapy feature that is enabled by your home care provider to provide pressure relief during exhalation.

Standby State

The state of the device when power is applied but the airflow is turned off.

8. Model

Model	Product Description			
	Product Contents	Work Mode	Size (mm)	Weight
E-20A-H-O	Main device (3.5-inch LCD), Tube	CPAP, AUTO	170(W)×196(D)×118(H)	1.5 kg
E-20AJ-H-O	Main device (2.4-inch LCD), Tube		170(W)×196(D)×118(H)	1.5 kg

9. Package Contents

After unpacking the system, make sure you have everything shown here:

No.	Articles	Num.	Notes
1	Main Device	1	
2	Humidifier	1	Optional
3	Shield	1	
4	Air Filter	2	
5	Power Adapter	1	
6	Power Cord	1	
7	Mask	1	
8	Tube	1	
9	SD Card	1	Optional
10	Carrying Case	1	
11	User Manual	1	
12	Quick Operation Manuel	1	
13	Warranty Card	1	

All parts and accessories do not contain latex.
The expected service life of the main device is 5 years.

IMPORTANT!

- If any of the above parts are missing, contact your home care provider.
- Contact your home care provider for additional information on the available accessories of this device. When using optional accessories, always follow the instructions enclosed with the accessories.

WARNINGS!

- This device should only be used with the mask and accessories manufactured or recommended by BMC or with those recommended by your prescribing physician. The use of inappropriate masks and accessories may affect the performance of the device and impair the effectiveness of therapy.
- The use of accessories other than those specified, with the exception of cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.
- All parts and accessories do not contain latex.

10. System Features

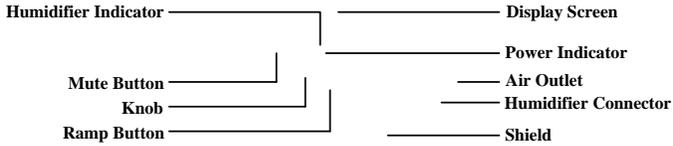


Fig. 10-1

Name	Function
Humidifier Indicator	Indicate the humidity level. There are five levels in total. The number of blue indicator lights that light up is directly proportional to the humidity level. If none of the indicator lights light up, it means the humidifier is turned off.
Mute Button	Press this button to mute the alert. However, if the problem causing the alert is not solved, the alert will sound again two minutes later.
Knob	Start treatment and adjust device settings
Ramp Button	Enable the Ramp feature
Display Screen	Display menus for operation, messages, monitoring data, etc.
Power Indicator	Indicate the power supply status with the green indicator light.
Air Outlet	Deliver pressurized air; connected to the tube or the air inlet of the humidifier
Humidifier Connector	Provide power to the humidifier which is connected to the main device
Shield	Connect the humidifier to the main device after this shield is removed.

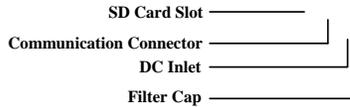


Fig. 10-2

Name	Function
SD Card Slot	Insert the SD card into this slot
Communication Connector	Connected to external equipment
DC Inlet	An inlet for the DC power supply
Air Filter and Filter Cap	Place the cap on the air filter, which is used to filter dust and pollen in the air entering the device.

11. First Time Setup

11.1 Placing the Device

Place the device on a firm, flat surface.

WARNINGS!

- If the device has been dropped or mishandled, if the enclosure is broken, or if water has entered the enclosure, disconnect the power cord and discontinue use. Contact your home care provider immediately.
- If the room temperature is warmer than 95°F (35°C), the airflow produced by the device may exceed 109.4°F (43°C). The room temperature must be kept below 95°F (35°C) while the patient uses the device.

CAUTIONS!

- If the device has been exposed to either very hot or very cold temperatures, allow it to adjust to room temperature (approximately 2 hours) before beginning setup.
- Make sure the device is away from any heating or cooling equipment (e.g., forced air vents, radiators, air conditioners).
- The device is not suitable for use in high humidity environments. Make sure that no water enters the device.
- Make sure that bedding, curtains, or other objects (such as pests) are not blocking or entering the filter or vents of the device.
- Keep pets or children away from the device.
- To avoid explosion, this device must not be used in the presence of flammable gases (e.g. anesthetics).
- Tobacco smoke may cause tar build-up within the device, leading to the malfunctioning of

the device.

- Air must flow freely around the device for it to work properly.

11.2 Installing the Air Filter and Filter Cap

- (1) Attach the air filter to the filter cap, as shown in Fig.11-1.

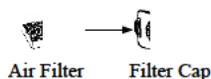


Fig. 11-1

- (2) Install the filter cap containing the air filter to the main device, as shown in Fig.11-2.

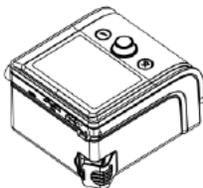


Fig. 11-2

CAUTION!

- The air filter must be in place when the device is operating.
- Installing the air filter and filter cap, device must be unplugged.

11.3 Connecting to Power

- (1) Insert the plug of the power adapter into the DC Inlet on the back of the device;
- (2) Connect the power cord to the power adapter;
- (3) Plug the other end of the power cord into the power outlet.

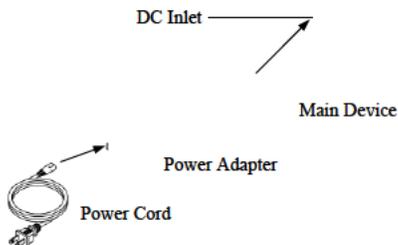


Fig. 11-3

WARNINGS!

- The device is powered on for use when the power cord and power adapter is connected. The **Knob**  turns the blower On/Off.

- Use of the device at an AC voltage beyond the stated range (see Section 5 "AC Power Consumption") may damage the device or cause device failure

CAUTION!

- Inspect the power cord often for any signs of damage. Replace a damaged cord immediately.

IMPORTANT!

- After interruption and restoration of the power supply, the device will restore its pre-interruption working status automatically.
- To remove AC power, disconnect the power cord from the power outlet.

11.4 Assembling the Tube and Mask

(1) Connect one end of the tube to the air outlet of the main device, as shown in Fig.11-4. If the main device is used with a humidifier, connect one end of the tube to the air outlet of the humidifier, as shown in Fig.11-5.

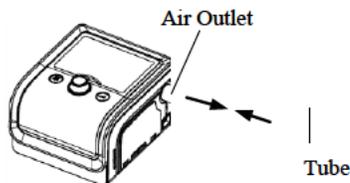


Fig. 11-4

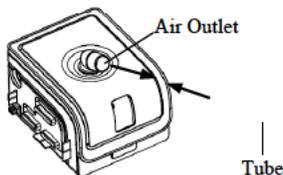


Fig. 11-5

(2) Connect the other end of the tube to the mask according to the user manual for the mask. Wear the mask.

WARNINGS!

- If multiple persons are going to use the device (e.g., rental devices), a low-resistance, main flow bacteria filter should be installed in-line between the device and tube. Pressures must be verified by your home care provider when alternate or optional accessories are in place.
- If you are using a mask with a built-in exhalation port, connect the mask's connector to the tube.
- If you are using a mask with a separate exhalation port, connect the tube to the exhalation

port. Position the exhalation port so that the vented air is blowing away from your face. Connect the mask's connector to the exhalation port.

- If you are using a full-face mask (a mask covering both your mouth and nose), the mask must be equipped with a safety (entrainment) valve.
- In order to minimize the risk of CO₂ rebreathing, the patient should observe the following instructions:
 - Use the accompanying tube and mask provided by BMC.
 - Do not wear the mask for more than a few minutes while the device is not operating.
 - Use only masks with vent holes. Do not block or try to seal the vent holes in the exhalation port.

11.5 Using Oxygen with the Device

Oxygen may be added at the mask connection. Please observe the instructions listed below when using oxygen with the device.

WARNINGS!

- Connect the oxygen tube to the oxygen inlet of the mask.
- The oxygen supply must comply with the local regulations for medical oxygen.
- Turn on the device before turning on the oxygen. Turn off the oxygen before turning off the device. Explanation of Warning: When the device is turned off, but the oxygen flow still exists, oxygen may accumulate within the device's enclosure and pose a fire hazard. Turning off the oxygen before turning off the device will prevent oxygen accumulation in the device and reduce the risk of fire. This warning applies to most CPAP devices.
- Oxygen supports combustion. Keep the device and the oxygen container away from heat, open flames, any oily substances, or other sources of ignition. DO NOT smoke in the area near E-20A or the oxygen container.
- Sources of oxygen should be located more than 1 m from the device.

11.6 Inserting the SD Card

Insert the SD card into the SD Card Slot, as shown in Fig.11-6.

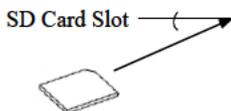


Fig. 11-6

If the SD card is inserted correctly, a symbol indicating correct insertion will appear in the Main Interface on the screen of the device, as shown in Fig.11-7.

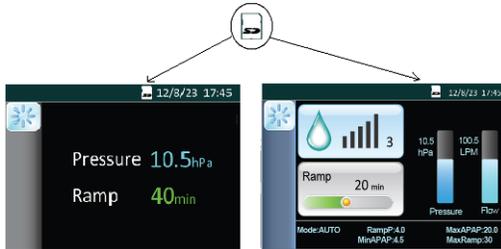


Fig. 11-7

If the SD card is inserted incorrectly or not inserted, a symbol indicating incorrect insertion or no SD card present will appear in the Main Interface on the screen of the device, as shown in Fig.11-8.

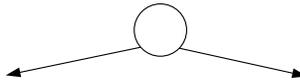


Fig. 11-8

CAUTION!

- To avoid data loss or any damage to the SD card, the SD card can only be removed after the main device stops delivering air.

11.7 Using the H60 Heated Humidifier

The H60 Heated Humidifier is available from your home care provider. The humidifier may reduce nasal dryness and irritation by adding moisture (and heat if applicable) to the airflow. For detailed information about the heated humidifier, please see the user manual for the heated humidifier.

11.8 Starting Treatment

Connect the device to a power outlet, press **the Knob** , and the device will start delivering air.

WARNINGS!

- Be sure to follow your physician's instructions on adjusting the settings! To order any accessories not included with this device, contact your equipment supplier.
- DO NOT connect any ancillary equipment to this device unless recommended by BMC or

your physician. If you suffer from chest discomfort, shortness of breath, stomach bloating, or severe headache when using the device, contact your physician or qualified medical personnel immediately.

12. Routine Use

12.1 Connecting the Tube

Connect the power cord, power adapter, and tube properly according to the instructions in the First Time Setup (Chapter 11). Connect the mask and headgear according to the user manual for the mask.

CAUTION!

- Before each use, examine the tube for any damage or debris. If necessary, clean the tube to remove the debris. Replace any damaged tube. Make sure that the mask does not leak.

12.2 Adjusting the Tube

Lie down on your bed, and adjust the tube so it is free to move if you turn during sleep. Adjust the mask and headgear until you have a comfortable fit and until there are no airflow leaks into your eyes.

12.3 Turning on the Airflow

Press **the Knob**  to turn on the airflow. The screen will display treatment pressure and other information.

12.4 Heating the Water in the Humidifier

Pay attention to the humidifier indicator lights when using the device with a humidifier. The indicator lights indicate the On/Off state of the humidifier. It is off when all indicator lights go out.

CAUTION!

- Observe the water level of the water chamber before using the humidifier. Make sure there is sufficient water in the water chamber, and avoid heating the humidifier with an empty water chamber.

12.5 Using the Ramp Button

Every time **the Ramp Button**  is pressed, the pressure will drop to the initial pressure, and then gradually rise to the prescribed treatment pressure according to the preset ramp time, so as to make the patient fall asleep easily. The screen displays a real-time countdown of the remaining ramp time in minutes.

CAUTIONS!

- You can press **the Ramp Button**  as often as you wish during sleep.

- The ramp feature is not prescribed for all users.

12.6 Turning the Device Off

Take off the mask and headgear, press and hold **the Knob** for two seconds, and the device will stop delivering air. Disconnect the power cord from the power outlet to power off the device.

CAUTION!

- If the airflow from the device is cold, place the tube under your quilt to reduce heat loss while you sleep.
- Do not position the device so that it is difficult to operate the disconnection device.
- To isolate the device from the supply mains, disconnect the plug.

13. Navigating the Patient Menu

13.1 Steps to Navigating the Patient Menu

13.1.1 Accessing the Main Interface

Connect the power cord and power adapter properly. The screen displays the Main Interface shown in Fig.13-1



Fig. 13-1



Fig. 13-2

13.1.2 Bringing up the Initial Setup Interface

From the Main Interface shown in Fig.13-1 or Fig.13-2, or when the device delivers air, press and hold **the Ramp Button** for three seconds. The screen displays the Initial Setup Interface of the Patient Menu, as shown in Fig.13-3.



Fig. 13-3

The first icon  on the left side of the screen indicates the Main Interface, and the second icon  indicates the Initial Setup Interface. As you turn **the Knob** , the cursor switches between the two icons, and the interface displayed on the screen changes accordingly.

13.1.3 Accessing the Setup Interface

When the cursor is on the icon , the screen displays the Setup Interface. Access the Setup Interface by pressing **the Knob** . The first option on the Setup Interface is then displayed in blue, as shown in Fig.13-4.



Fig. 13-4

13.1.4 Selecting Options

As you turn **the Knob**  clockwise, the cursor moves downwards from one option to another. As you turn it counterclockwise, the cursor moves upwards. When the cursor is on a certain option, press **the Knob** , and the option is then displayed in yellow, meaning that the option can now be adjusted, as shown by the **Heater** option in Fig.13-5.

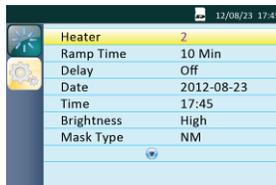


Fig. 13-5

13.1.5 Adjusting Options

Adjust the option by turning **the Knob** . As shown in Fig.13-5, the **Heater** option is selected. As you turn **the Knob**  clockwise, the numbering increases, indicating a higher humidity level. As you turn **the Knob**  counterclockwise, the numbering decreases, indicating a lower humidity level. At this moment, the **Heater** option is still displayed in yellow, as shown in Fig.13-6.

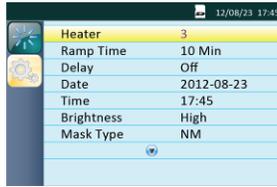


Fig. 13-6

13.1.6 Confirming Adjustments

Confirm your adjustment to an option by pressing **the Knob**. The option is then displayed in blue, as shown in Fig.13-7.



Fig. 13-7

13.1.7 Turning Pages

When the cursor is on **Mask Type**, the last option shown in Fig.13-7, the remaining options will appear on a new page if you continue to turn **the Knob** clockwise, as shown in Fig.13-8.

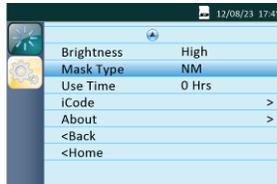


Fig. 13-8

Note:   are page turning symbols.

13.1.8 Exiting the Patient Menu

(1) Returning to the Initial Setup Interface

Move the cursor to the **Back** option by turning **the Knob**, as shown in Fig.13-9.

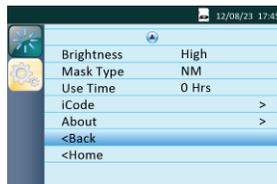


Fig. 13-9

Press **the Knob**, the cursor jumps to the second icon  on the left side of the screen. The screen displays the Initial Setup Interface, as shown in Fig.13-10.



Fig. 13-10

(2) Returning to the Main Interface

Move the cursor to the **Home** option by turning **the Knob**, as shown in Fig.13-11.

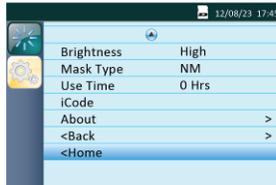


Fig. 13-11

Press **the Knob** to exit the Patient Menu. The screen will display the Main Interface shown in Fig.13-1 or Fig.13-2.

13.2 Options of the Patient Menu and Corresponding Descriptions

Option	Range	Description
Heater	Off, 1-5	There are five humidity levels available. As the numbering increases, the humidity rises accordingly. "Off" means the humidifier is turned off. The default setting is "2."
RESlex	Off, 1-3	This feature enables the device to automatically reduce the treatment pressure when the patient exhales, so as to make the user more comfortable. The higher the numbering is, the more pressure the device reduces. "Off" means this feature is disabled. The default setting is "Off."
Ramp Time	0-Ramp Max	In order to increase comfort and help the patient fall asleep easily, the pressure can increase gradually, when the Ramp feature is enabled. The ramp time during which the initial pressure rises to the prescribed treatment pressure can be adjusted. As you turn the Knob to the nearest point, the numbering increases or decreases by five minutes. The default setting is "10 minutes." The screen displays a real-time countdown of the remaining ramp time in minutes.
Delay	On/Off	When the humidifier is on, this feature allows the airflow to continue for about 15 minutes at a low pressure (about 2 hPa) after you press the Knob to discontinue treatment. This will blow off the vapor left in the humidifier to avoid any damage to the device. When this feature is set to "Off," which means it is disabled, the airflow stops delivering air instantly after you press the Knob . The default setting is "Off."
Date	2000-01-01 — 2099-12-31	Setting date by adjusting this option.
Time	—	Setting time by adjusting this option.
Brightness	High/Low	Setting screen brightness by adjusting this option. The default setting is "High."
Mask Type	FM; NM; PM; A, B, C	There are three mask types available, namely FM (full-face mask), NM (nasal mask), and PM (nasal pillow mask). The default mask type is "NM," but the patient can choose other suitable masks as well. When selecting masks other than the above three types of BMC masks, the patient can identify the masks as A, B, or C.
Use Time	0-50000 Hrs	Use Time displays how long has the device been used by the user. The use time can be erased.
iCode	iCode I, iCode II	iCode provides access to the patient's compliance data during a recent time period. The iCode I mode displays data in sequences of characters, and the iCode II mode displays data in two-dimensional codes.

14. Alert

Alert Message	Description
Loss of Power!!!	An audible alert will sound if the device is accidentally disconnected from power when it is delivering air. Note: (1) The alert will not sound if power failure occurs when the device is in standby state. (2) No alert message on the screen during a power failure.
Ventilator Inoperative!!!	An audible alert will sound if no airflow comes out of the machine; the screen will display " Ventilator Inoperative!!! "
Leak!!	When the airflow is on, an audible alert will sound if the air leak rate exceeds 150 l/min; the screen will display " Leak!! "
Low Input Voltage!!	If you use a battery rather than an external power adapter to power the device, an audible alert will sound when the battery is low; the screen will display " Low Input Voltage!! "
Humidifier Failure!!	when humidifier is applied, an audible alert will sound when the humidifier fails to work; the screen will display " Humidifier Failure!! "
Please Replace Filter!	When the Filter Alert feature is enabled, an audible alert will sound if an air filter has been used for more than six months; the screen will display " Please Replace Filter! "
SD Card Full!	The screen will display " SD Card Full! " if the SD card has reached its maximum capacity.
Remove and Reinsert!	The screen will display " Remove and Reinsert! " if the SD card fails to work.

15. Cleaning and Disinfection

WARNINGS!

- Regular cleaning of the device and its accessories is very important for the prevention of respiratory infections.
- To avoid electric shock, always unplug the device before cleaning.
- Use washing liquid that is nontoxic to humans and does not cause allergies in humans.
- Follow the manufacturer's instructions on cleaning the mask and tube and on determining the frequency of cleaning.
- Before cleaning, check whether the device has been disconnected from the power supply, whether the power cord has been unplugged, and whether the water chamber of the humidifier has cooled down. Make sure the heater plate has cooled down to room temperature, so you do not get burned.

CAUTIONS!

- Overheating of the materials could lead to early fatigue of these materials.
- Do not use solutions containing chlorinated lime, chlorine, or aromatic to clean the device and its accessories. Liquid soap containing the humidifying agent or antimicrobials should not be used either. These solutions may harden cleaned materials or reduce their life.
- Do not clean or dry the device and its accessories when the temperature is higher than 80°C(176°F). High temperatures could reduce product life.
- Do not immerse the device in any fluids.

15.1 Cleaning the Mask and Headgear

For details, refer to the cleaning instructions in the user manual for the mask.

15.2 Cleaning the Water Chamber of the Humidifier

For details, refer to the cleaning instructions in the user manual for the humidifier.

15.3 Cleaning the Enclosure

Wipe the surface of the device with a soft, slightly damp cloth.

CAUTION!

- The device can only be used after the enclosure is dry, so that no moisture enters the device.

15.4 Cleaning the Tube

- (1) Remove the tube from the device and mask before cleaning.
- (2) Clean the tube in warm water which contains washing liquid, and then rinse it in clean water thoroughly.
- (3) After cleaning, air-dry the tube in a cool, well-ventilated area, and avoid direct sunlight. It takes approximately 30 minutes to completely air-dry the tube. Check whether the tube is

completely dry before re-use.

15.5 Replacing the Air Filter

- (1) Open the air filter cap to remove the air filter.
- (2) Put the new air filter in the filter area, and then place the filter cap back properly.

CAUTIONS!

- To avoid material damage, do not place the spare air filter in direct sunlight, humid environments, or temperatures below the freezing point. The air filter should be replaced every 6 months (It may be replaced more frequently based on actual sanitary conditions).
- Operating the device with a dirty air filter may stop it from working properly and may cause damage to the device.
- Replacing the air filter and filter cap, device must be unplugged.

15.6 Disinfection

Generally speaking, if you have strictly followed the above cleaning instructions, you do not have to disinfect the device and/or humidifier. If the device is contaminated or used in clinical trials, you may purchase disinfectants from a pharmacist to disinfect the device.

See the Disinfection section of the humidifier user manual for more information on the disinfection of the water chamber.

CAUTIONS!

- Disinfectants tend to damage materials and reduce the life of components. Try to select the appropriate disinfectant, and follow the disinfectant manufacturer's instructions and recommendations.
- After disinfection, check the disinfected component for any signs of damage. Replace any damaged component immediately.

WARNINGS!

- After disinfection, rinse any disinfected component in clean water thoroughly, especially components in close contact with the patient such as the mask, headgear, and tube, so as to prevent disinfectant residuals from damaging the skin or respiratory tract or causing allergies.
- The device shall not be serviced or maintained while in use with a patient.
- Sterilization of this device and its components other than recommended is not permitted.

16. Traveling with the Device

CAUTIONS!

- Empty the water chamber of the humidifier before packing the device for your trip; in order to prevent any remaining water from entering the device.
- Using the device at an incorrect elevation setting could result in airflow pressures higher than the prescribed setting. Always verify the elevation setting when traveling or relocating.
- If the device is used when the atmospheric pressure is out of the stated range (See Section 5), the accuracy of the leakage alert will be affected.

(1) Use the BMC carrying case to carry the device and accessories along with you. Do not put them in your checked baggage.

(2) This device operates on power supplies of 100-240 V and 50/60 Hz, and is suitable for use in any country in the world. No special adjustment is necessary, but you will need to find out the types of the power sockets in your destination. Bring, if necessary, a power socket adaptor which can be bought in electronics stores.

(3) Remember to bring a spare air filter and the emergency documents (filled and signed by your physician) about this device. If you plan to travel by air, remember to bring the multi-language emergency documents about respiratory therapy, in case that the border and customs officers in your destination country inspect the device. With the emergency documents, you can prove to them that it is a medical device.

(4) Security Stations: For convenience at security stations, there is a note on the bottom of the device stating that it is medical equipment. It may be helpful to bring this manual along with you to help security personnel understand the device.

17. Transferring the Device to Another Patient

If the device is transferred to another patient, components in close contact with the previous owner, including the mask, headgear, tube, and air filter, should be cleaned and disinfected to prevent cross-infection.

18. Reordering

Contact your home care provider to order accessories or replacement filters.

The device does not require routine servicing.

WARNINGS!

- If you notice any unexplained changes in the performance of the device, if it is making unusual or harsh sounds, if it has been dropped or mishandled, if the enclosure is broken, or if water has entered the enclosure, discontinue use. Contact your home care provider.
- If the device malfunctions, contact your home care provider immediately. Never attempt to open the enclosure of the device. Repairs and adjustments must be performed by BMC-authorized service personnel only. Unauthorized service could cause injury, invalidate the warranty, or result in costly damage.
- If necessary, contact your local authorized dealer or BMC Medical Co., Ltd. for technical support and documents.

19 Technical Support

Please contact BMC directly if you need the circuit diagram of the device and the list of components for certain purposes such as maintenance or connection to other equipment. BMC will provide the circuit diagram and/or other technical documents in whole or in part according to your needs.

20. Disposal

When the device reaches the end of its service life, dispose of the device and packaging in accordance with local laws and regulations.

21. Troubleshooting

The table below lists common problems you may have with the device and possible solutions to those problems. If none of the corrective actions solve the problem, contact your home care provider.

21.1 Common Problems in Patients and Corresponding Solutions

Problem	Possible Cause	Solution(s)
Dry, cold, runny, and blocked nose; having a cold	The nose reacts to the airflow and cold. Due to fast airflow, the air becomes cold, leading to nasal mucosa irritation and subsequent dryness and swelling.	Increase the humidity setting of the humidifier. Contact your physician, and continue treatment unless the physician suggests the opposite.
Dry mouth and throat	Probably because the patient sleeps with his or her mouth open, and the pressurized air goes out via the mouth, leading to nasal and throat dryness.	Use a chin strap to prevent the mouth from opening during sleep, or use a full-face mask. Contact your physician for details.
Eye irritation	The mask size or model may not be correct, or the mask is not positioned correctly, thereby leading to air leakage.	Narrow the distance between the forehead support of the mask and the forehead. Note that adjusting the mask too tight may leave markings on the patient's face. Add additional filling to the mask so it does not leak. Contact your equipment supplier for an appropriate mask. Add additional filling to the mask if necessary.
	Mask cushion (the soft part of the mask) hardens.	Replace the mask or mask cushion.
Facial reddening	The mask is too tight.	Loosen the headgear.
	The distance between the forehead support of the mask and the forehead is not correct.	Try a different distance. The angle and size of the forehead support differ according to the type of masks.
	Wrong mask size	Contact your equipment supplier for a correct-size mask.
	The patient is allergic to the materials of the mask.	Contact your physician and equipment supplier. Use a latex-free mask. Place a lining between the skin and mask.

Water in mask	When the humidifier is used, the humidified air tends to condense in the cold tube and mask if the room temperature is low.	Turn the humidity setting down, or raise the room temperature. Place the tube under the quilt, or use the tube cover. Hang the tube loosely, and the lowest part of the tube should be lower than the patient's head.
Nasal, sinus, or ear pain	Sinus or middle ear inflammation	Contact your physician immediately.
Discomfort due to inability to adapt to the treatment pressure	The patient will feel uncomfortable when the treatment pressure is higher than 13 hPa. However, the treatment pressure is determined according to the patient's conditions, and cannot treat sleep apnea if the treatment pressure is set too low.	It takes a maximum of four weeks to adapt to pressurized air. Relax and breathe through the nose. If the problem still exists, contact your physician.
Obstructive sleep apnea symptoms recur.	Probably because the patient sleeps with his or her mouth open, and the pressurized air goes out via the mouth, leading to blockage in the respiratory tract.	Use a chin strap to prevent the mouth from opening during sleep, or use a full-face mask. Contact your physician for details.
The device is too noisy.	The tube is not connected properly.	Reconnect the tube properly.
Air delivered from the device is abnormally hot.	The air inlet of the device may be partially blocked, leading to insufficient airflow into the device.	Replace the air filter (see 15.5 Replacing the Air Filter), and clean the air inlet. Place the device in an area where air flows freely, and make sure the device is at least 20 centimeters away from the wall, curtain, or other things.

21.2 Common Problems in the Device and Corresponding Solutions

Problem	Possible Cause	Solution(s)
The device does not work when it is turned on.	The Auto On/Off feature is enabled	Take a few deep breaths with the mask on, and the device will start automatically.
	Power is not connected properly.	Ensure that the power cord, power adapter, and the device are connected properly.
	There is no voltage.	Check whether a power outage occurs by turning on a light or other means. If you are sure the fuse in the device is broken, contact your equipment supplier for repair.
	Cannot find any cause.	Contact your equipment supplier.
The device is working, but the pressure inside the mask differs from the set treatment pressure.	The tube is not connected properly.	Reconnect the tube properly.
	There may be holes in the mask or pressure sensing tube.	Contact your equipment supplier.
	It is a faulty device.	Contact your equipment supplier.
The device produces very low pressures.	The air inlet of the device may be blocked.	Replace the air filter (see 15.5 Replacing the Air Filter), and clean the air inlet. Make sure the air inlet is unblocked.
	The treatment pressure has been changed accidentally.	Contact your physician.
	When the Ramp feature is enabled, it takes some time for the initial pressure to rise to the treatment pressure. This is normal.	If necessary, disable the Ramp feature, or set the ramp time shorter.
After the device is turned on, the screen displays intermittently, or displays nothing at all.	The operating system of the device needs to be readjusted or restarted.	Unplug the power cord of the device, and re-plug it 20 seconds later.
The device is in standby, and will not start.	The operating system of the device needs to be readjusted or restarted.	Unplug the power cord of the device, and re-plug it 20 seconds later.

22. EMC Requirements

Guidance and manufacturer's declaration - electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The user of the device should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical home or hospital.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical home or hospital.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or from a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	If the pressure deviates more than is indicated in the device specifications, it may be necessary to position the device further from sources of power frequency magnetic fields. The power frequency magnetic field should be measured in the intended installation location to ensure that it is sufficiently low.
Note: U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 Vrms</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d=1.2\sqrt{P}$ $d=1.2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d=2.3\sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applied.

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

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

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

Recommended separation distances between portable and mobile RF communications equipment and the device

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

Rated maximum output of transmitter W	150 kHz~80 MHz $d=1.2\sqrt{P}$	80 MHz~800 MHz $d=1.2\sqrt{P}$	800 MHz~2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

23. Limited Warranty

3B Medical, Inc.(hereafter '3B') warrants that the RESmart® CPAP and Auto-CPAP devices will be free of all defects in workmanship and materials, and will perform according to specifications, for a period of two (2) years from the date of sale of the device, and 90 days on any accessories.

If the product fails to perform in accordance with the product specifications, 3B will repair or replace at its option, the defective material or part. This warranty *does not* cover damage caused by accident, misuse, abuse, alteration and other defects not related to material or workmanship.

- 3B will issue an RMA (Return Merchandise Authorization) within 24 hours of receipt of written notification of a failed or defective unit. Failed/defective units must be returned within 30 days of the RMA date.
- Shipping the machine to us for warranty diagnostic is the customer's responsibility. Warranty covers Domestic Shipping back to you. Please contact us for all warranty claims or questions.
- This warranty coverage is applicable to all 3B/BMC CPAP, Auto CPAP and Auto Bi-level devices.
- The warranty policy *does not* cover any damages caused as a result of alteration, intentional damage, modification, or unauthorized repair of the device.
- Warranty *does* include reasonable water damage and is at the sole discretion of 3B.
- This warranty replaces all other expressed or implied warranties, including any implied warranty of merchantability or fitness for a particular purpose. 3B reserves the right to amend this policy at any time.

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3B™

E-20C System

User Manual



CE 0123

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1. Symbols

1.1 Control Buttons

-  Ramp Button
-  Mute Button
-  Knob

1.2 Device Symbols

-  Operating Instructions
-  Type BF Applied Part (mask)
-  Class II (Double Insulated)
-  AC Power
-  DC Power
- IP22** ≥ 12.5 mm Diameter, Dripping (15° tilted)
-  Hot Surface
-  Serial Number of the Product
-  Manufacturer
-  Authorized Representative in the European Community
-  European CE Declaration of Conformity
-  SD Card
-  Water Filling Prohibited Here
-  Water Inlet
-  Directional Indicator for Removing the Water Inlet Cap
-  Directional Indicator for Screwing the Water Inlet Cap

2. Warning, Caution and Important Tip

WARNING!

Indicate the possibility of injury to the user or operator.

CAUTION!

Indicate the possibility of damage to the device.

IMPORTANT TIP!

Place emphasis on an operating characteristic.

Warnings, Cautions, and Important Tips appear throughout this manual as they apply.

3. Intended Use

The E-20C system is a CPAP (Continuous Positive Airway Pressure) device designed for the treatment of adult Obstructive Sleep Apnea (OSA) only.

The device is to be used only on the instruction of a licensed health care professional. Your home care provider will make the correct pressure settings according to your health care professional's prescription.

Several accessories are available to make your OSA treatment with this device as convenient and comfortable as possible. To ensure that you receive the safe, effective therapy prescribed for you, use only BMC accessories.

WARNINGS!

- This device is intended for adult use only.
- This device is not intended for life support.
- The instructions in this manual are not intended to supersede established medical protocols.

CAUTION!

- This device is restricted to sale by or on the order of a physician.
- The device is intended for use by operators trained or experienced in similar equipment.
- The patient is an intended operator.
- Cleaning and disinfection can be performed by the patient.

IMPORTANT!

- Read and understand the entire user manual before operating this system. If you have any questions concerning the use of this system, contact your home care provider or health care professional.

4. Contraindications

Studies have shown that the following pre-existing conditions may contraindicate the use of positive airway pressure therapy for some patients:

Absolute Contraindications: pneumothorax, mediastinal emphysema; cerebrospinal fluid leak, traumatic brain injury, or pneumocephalus; shock caused by a variety of conditions before treatment; active epistaxis; upper gastrointestinal bleeding before treatment; coma or impaired consciousness making the use of mask during therapy impossible; giant vocal fold polyp, etc.

Relative Contraindications: severe coronary heart disease complicated with left ventricular failure, acute otitis media, excessive respiratory secretions and weak cough, weak spontaneous breathing, nasal or oral tracheal intubation and tracheotomy, severe nasal congestion caused by a variety of conditions, lung bullae, and allergies to breathing masks, etc.

The following side effects may occur during treatment:

- Dryness of the mouth, nose and throat
- Abdominal bloating
- Ear or sinus discomfort
- Eye irritation
- Skin irritation due to the use of a mask
- Chest discomfort

IMPORTANT!

- An irregular sleep schedule, alcohol consumption, obesity, sleeping pills, or sedatives may aggravate your symptoms.

CAUTION!

- Contact your health care professional if symptoms of sleep apnea recur. Contact your health care professional if you have any questions concerning your therapy.

5. Specifications

Device Size

Dimensions: 170 mm× 196 mm× 118 mm, or 290 mm× 196 mm× 134 mm (with the humidifier)

Weight: 1.5 kg, or 2.5 kg(with the humidifier)

Product Use, Transport and Storage

	Operation	Transport and Storage
Temperature:	5 to 35°C (41°F to 95°F)	-20 to 55°C (-4°F to 131°F)
Humidity:	15% to 93% Non-condensing	15% to 93% Non-condensing
Atmospheric Pressure:	760-1060 hPa	760-1060 hPa

Mode of Operation

Continuous

Work Mode

CPAP

SD Card

With a capacity \geq 2 G, the SD card can record patient data and fault information. Furthermore, the language pack stored on the SD card enables you to change the language of the device.

AC Power Consumption

100–240 V AC, 50/60 Hz, 2.0 A max

Type of Protection Against Electric Shock

Class II Equipment

Degree of Protection Against Electric Shock

Type BF Applied Part

Degree of Protection Against Ingress of Water

IP22

Pressure Range

4 to 20 hPa (in 0.5 hPa increments), \leq 30 hPa under single fault conditions.

Pressure Display Accuracy

$\pm(0.5 \text{ hPa} + 4\%)$

Pressure Stability

4 to 20 hPa ($\pm 1 \text{ hPa}$)

Ramp

The ramp time ranges from 0 to 60 minutes

Sound Pressure Level

$< 30 \text{ dB}$, when the device is working at the pressure of 10 hPa.

Sound Power Level

<38 dB, when the device is working at the pressure of 10 hPa.

Maximum Flow

Test Pressure (hPa)	4	9	15	20
Average Flow at the Patient Connection Port (l/min)	80	92	91	96

Tube

Length: 1.8 m (± 0.18 m)

The Form and the Dimensions of the Patient Connection Port

The 22 mm conical air outlet complies with ISO 5356-1

6. Available Therapy

The device delivers the following therapy:

CPAP- Delivers Continuous Positive Airway Pressure; CPAP maintains a constant level of pressure throughout the breathing cycle. If your health care professional has prescribed ramp for you, you can press the **Ramp Button**  to reduce the pressure and then gradually increase the pressure to the therapeutic pressure setting so that you can fall asleep more comfortably.

7. Glossary

Apnea

A condition marked by the cessation of spontaneous breathing.

Auto Off

When this feature is enabled, the device automatically discontinues therapy whenever the mask is removed.

Auto On

When this feature is enabled, the device automatically initiates therapy when you breathe into the mask.

CPAP

Continuous Positive Airway Pressure

iCode

A feature that is intended to give access to compliance and therapy management information. The "iCode" consists of six separate codes displayed in the Patient Menu. iCode I displays sequences of characters, and iCode II displays two-dimensional codes.

LPM

Liters Per Minute

OSA

Obstructive Sleep Apnea

Patient Menu

The display mode in which you can change patient-adjustable device settings, such as the starting pressure for the Ramp feature.

Ramp

A feature that may increase patient comfort when therapy is started. It can reduce pressure and then gradually increase the pressure to the prescription setting so the patient can fall asleep more comfortably.

RESlex

A therapy feature that is enabled by your home care provider to provide pressure relief during exhalation.

Standby State

The state of the device when power is applied but the airflow is turned off.

8. Model

Model	Product Description			
	Product Contents	Work Mode	Size (mm)	Weight
E-20C-H-O	Main device, Tube	CPAP	170(W)×196(D)×118(H)	1.5 kg

9. Package Contents

After unpacking the system, make sure you have everything shown here:

No.	Articles	Num.	Notes
1	Main Device	1	
2	Humidifier	1	Optional
3	Shield	1	
4	Air Filter	2	
5	Power Adapter	1	
6	Power Cord	1	
7	Mask	1	
8	Tube	1	
9	SD Card	1	Optional
10	Carrying Case	1	
11	User Manual	1	
12	Quick Operation Manual	1	

All parts and accessories do not contain latex.
The expected service life of the main device is 5 years.

IMPORTANT!

- If any of the above parts are missing, contact your home care provider.
- Contact your home care provider for additional information on the available accessories of this device. When using optional accessories, always follow the instructions enclosed with the accessories.

WARNINGS!

- This device should only be used with the mask and accessories manufactured or recommended by BMC or with those recommended by your prescribing physician. The use of inappropriate masks and accessories may affect the performance of the device and impair the effectiveness of therapy.
- The use of accessories other than those specified, with the exception of cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.

10. System Features

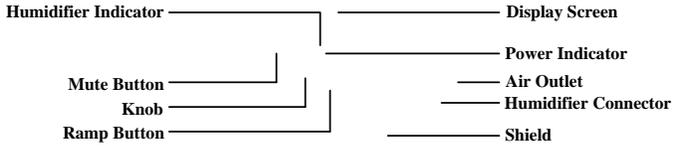


Fig. 10-1

Name	Function
Humidifier Indicator	Indicate the humidity level. There are five levels in total. The number of blue indicator lights that light up is directly proportional to the humidity level. If none of the indicator lights light up, it means the humidifier is turned off.
Mute Button	Press this button to mute the alert. However, if the problem causing the alert is not solved, the alert will sound again two minutes later.
Knob	Start treatment and adjust device settings
Ramp Button	Enable the Ramp feature
Display Screen	Display menus for operation, messages, monitoring data, etc.
Power Indicator	Indicate the power supply status with the green indicator light.
Air Outlet	Deliver pressurized air; connected to the tube or the air inlet of the humidifier
Humidifier Connector	Provide power to the humidifier which is connected to the main device
Shield	Connect the humidifier to the main device after this shield is removed.

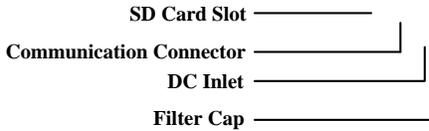


Fig. 10-2

Name	Function
SD Card Slot	Insert the SD card into this slot
Communication Connector	Connected to external equipment
DC Inlet	An inlet for the DC power supply
Air Filter and Filter Cap	Place the cap on the air filter, which is used to filter dust and pollen in the air entering the device.

11. First Time Setup

11.1 Placing the Device

Place the device on a firm, flat surface.

WARNINGS!

- If the device has been dropped or mishandled, if the enclosure is broken, or if water has entered the enclosure, disconnect the power cord and discontinue use. Contact your home care provider immediately.
- If the room temperature is warmer than 95°F (35°C), the airflow produced by the device may exceed 109°F (43°C). The room temperature must be kept below 95°F (35°C) while the patient uses the device.

CAUTIONS!

- If the device has been exposed to either very hot or very cold temperatures, allow it to adjust to room temperature (approximately 2 hours) before beginning setup.
- Make sure the device is away from any heating or cooling equipment (e.g., forced air vents, radiators, air conditioners).
- The device is not suitable for use in high humidity environments. Make sure that no water enters the device.
- Make sure that bedding, curtains, or other objects (such as pests) are not blocking or entering the filter or vents of the device.
- Keep pets or children away from the device.
- To avoid explosion, this device must not be used in the presence of flammable gases (e.g.

anesthetics).

- Tobacco smoke may cause tar build-up within the device, leading to the malfunctioning of the device.
- Air must flow freely around the device for it to work properly.

11.2 Installing the Air Filter and Filter Cap

(1) Attach the air filter to the filter cap, as shown in Fig.11-1.

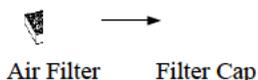


Fig. 11-1

(2) Install the filter cap containing the air filter to the main device, as shown in Fig.11-2.

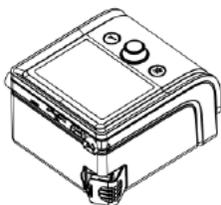


Fig. 11-2

CAUTION!

- The air filter must be in place when the device is operating.
- Installing the air filter and filter cap, device must be unplugged.

11.3 Connecting to Power

- (1) Insert the plug of the power adapter into the DC Inlet on the back of the device;
- (2) Connect the power cord to the power adapter;
- (3) Plug the other end of the power cord into the power outlet.

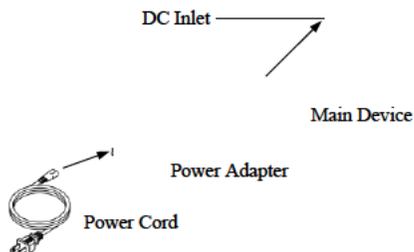


Fig. 11-3

WARNINGS!

- The device is powered on for use when the power cord and power adapter is connected. The **Knob** turns the blower On/Off.
- Use of the device at an AC voltage beyond the stated range (see Section 5 "AC Power Consumption") may damage the device or cause device failure.

CAUTION!

- Inspect the power cord often for any signs of damage. Replace a damaged cord immediately.

IMPORTANT!

- After interruption and restoration of the power supply, the device will restore its pre-interruption working status automatically.
- To remove AC power, disconnect the power cord from the power outlet.

11.4 Assembling the Tube and Mask

(1) Connect one end of the tube to the air outlet of the main device, as shown in Fig.11-4. If the main device is used with a humidifier, connect one end of the tube to the air outlet of the humidifier, as shown in Fig.11-5.

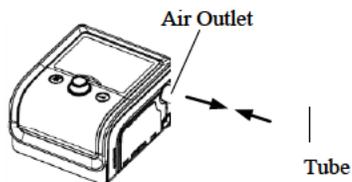


Fig. 11-4

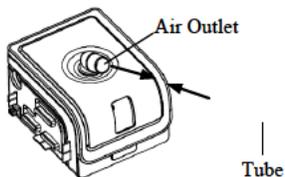


Fig. 11-5

(2) Connect the other end of the tube to the mask according to the user manual for the mask. Wear the mask.

WARNINGS!

- If multiple persons are going to use the device (e.g., rental devices), a low-resistance, main flow bacteria filter should be installed in-line between the device and tube. Pressures must

be verified by your home care provider when alternate or optional accessories are in place.

- If you are using a mask with a built-in exhalation port, connect the mask's connector to the tube.
- If you are using a mask with a separate exhalation port, connect the tube to the exhalation port. Position the exhalation port so that the vented air is blowing away from your face. Connect the mask's connector to the exhalation port.
- If you are using a full-face mask (a mask covering both your mouth and nose), the mask must be equipped with a safety (entrainment) valve.
- In order to minimize the risk of CO₂ rebreathing, the patient should observe the following instructions:
 - Use the accompanying tube and mask provided by BMC.
 - Do not wear the mask for more than a few minutes while the device is not operating.
 - Use only masks with vent holes. Do not block or try to seal the vent holes in the exhalation port.

11.5 Using Oxygen with the Device

Oxygen may be added at the mask connection. Please observe the instructions listed below when using oxygen with the device.

WARNINGS!

- Connect the oxygen tube to the oxygen inlet of the mask.
- The oxygen supply must comply with the local regulations for medical oxygen.
- Turn on the device before turning on the oxygen. Turn off the oxygen before turning off the device. Explanation of Warning: When the device is turned off, but the oxygen flow still exists, oxygen may accumulate within the device's enclosure and pose a fire hazard. Turning off the oxygen before turning off the device will prevent oxygen accumulation in the device and reduce the risk of fire. This warning applies to most CPAP devices.
- Oxygen supports combustion. Keep the device and the oxygen container away from heat, open flames, any oily substances, or other sources of ignition. DO NOT smoke in the area near E-20C or the oxygen container.
- Sources of oxygen should be located more than 1 m from the device.

11.6 Inserting the SD Card

Insert the SD card into the SD Card Slot, as shown in Fig.11-6.

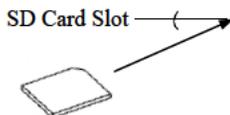


Fig. 11-6

If the SD card is inserted correctly, a symbol indicating correct insertion will appear in the

Main Interface on the screen of the device, as shown in Fig.11-7.



Fig. 11-7

If the SD card is inserted incorrectly or not inserted, a symbol indicating incorrect insertion or no SD card present will appear in the Main Interface on the screen of the device, as shown in Fig.11-8.

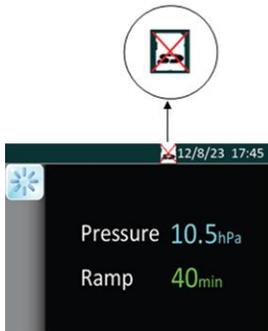


Fig. 11-8

CAUTION!

- To avoid data loss or any damage to the SD card, the SD card can only be removed after the main device stops delivering air.

11.7 Using the H60 Heated Humidifier

The H60 Heated Humidifier is available from your home care provider. The humidifier may reduce nasal dryness and irritation by adding moisture (and heat if applicable) to the airflow. For detailed information about the heated humidifier, please see the user manual for the heated humidifier.

11.8 Starting Treatment

Connect the device to a power outlet, press **the Knob** , and the device will start delivering air.

WARNINGS!

- Be sure to follow your physician's instructions on adjusting the settings! To order any accessories not included with this device, contact your equipment supplier.
- DO NOT connect any ancillary equipment to this device unless recommended by BMC or your physician. If you suffer from chest discomfort, shortness of breath, stomach bloating, or severe headache when using the device, contract your physician or qualified medical personnel immediately.

12. Routine Use

12.1 Connecting the Tube

Connect the power cord, power adapter, and tube properly according to the instructions in the First Time Setup (Chapter 11). Connect the mask and headgear according to the user manual for the mask.

CAUTION!

- Before each use, examine the tube for any damage or debris. If necessary, clean the tube to remove the debris. Replace any damaged tube. Make sure that the mask does not leak.

12.2 Adjusting the Tube

Lie down on your bed, and adjust the tube so it is free to move if you turn during sleep. Adjust the mask and headgear until you have a comfortable fit and until there are no airflow leaks into your eyes.

12.3 Turning on the Airflow

Press **the Knob**  to turn on the airflow. The screen will display treatment pressure and other information.

12.4 Heating the Water in the Humidifier

Pay attention to the humidifier indicator lights when using the device with a humidifier. The indicator lights indicate the On/Off state of the humidifier. It is off when all indicator lights go out.

CAUTION!

- Observe the water level of the water chamber before using the humidifier. Make sure there is sufficient water in the water chamber, and avoid heating the humidifier with an empty water chamber.

12.5 Using the Ramp Button

Every time **the Ramp Button**  is pressed, the pressure will drop to the initial pressure, and then gradually rise to the prescribed treatment pressure according to the preset ramp time, so as to make the patient fall asleep easily. The screen displays a real-time countdown of the remaining ramp time in minutes.

CAUTIONS!

- You can press **the Ramp Button**  as often as you wish during sleep.
- The ramp feature is not prescribed for all users.

12.6 Turning the Device Off

Take off the mask and headgear, press and hold **the Knob**  for two seconds, and the device will stop delivering air. Disconnect the power cord from the power outlet to power off the device.

CAUTION!

- If the airflow from the device is cold, place the tube under your quilt to reduce heat loss while you sleep.
- Do not position the device so that it is difficult to operate the disconnection device.
- To isolate the device from the supply mains, disconnect the plug.

13. Navigating the Patient Menu

13.1 Steps to Navigating the Patient Menu

13.1.1 Accessing the Main Interface

Connect the power cord and power adapter properly. The screen displays the Main Interface shown in Fig.13-1.



Fig. 13-1

13.1.2 Bringing up the Initial Setup Interface

From the Main Interface shown in Fig.13-1, or when the device delivers air, press and hold **the Ramp Button**  for three seconds. The screen displays the Initial Setup Interface of the Patient Menu, as shown in Fig.13-2.



Fig. 13-2

The first icon  on the left side of the screen indicates the Main Interface, and the second icon  indicates the Initial Setup Interface. As you turn **the Knob** , the cursor switches between the two icons, and the interface displayed on the screen changes accordingly.

13.1.3 Accessing the Setup Interface

When the cursor is on the icon , the screen displays the Setup Interface. Access the Setup Interface by pressing **the Knob** . The first option on the Setup Interface is then displayed in blue, as shown in Fig.13-3.

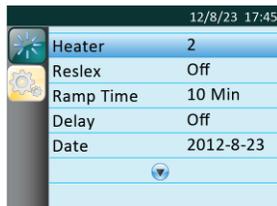


Fig. 13-3

13.1.4 Selecting Options

As you turn **the Knob** clockwise, the cursor moves downwards from one option to another. As you turn it counterclockwise, the cursor moves upwards. When the cursor is on a certain option, press **the Knob**, and the option is then displayed in yellow, meaning that the option can now be adjusted, as shown by the **Heater** option in Fig.13-4.

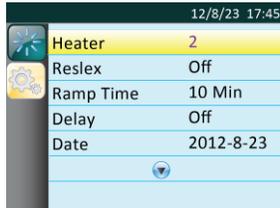


Fig. 13-4

13.1.5 Adjusting Options

Adjust the option by turning **the Knob**. As shown in Fig.13-4, the **Heater** option is selected. As you turn **the Knob** clockwise, the numbering increases, indicating a higher humidity level. As you turn **the Knob** counterclockwise, the numbering decreases, indicating a lower humidity level. At this moment, the **Heater** option is still displayed in yellow, as shown in Fig.13-5.

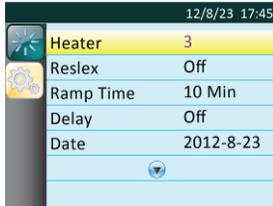


Fig. 13-5

13.1.6 Confirming Adjustments

Confirm your adjustment to an option by pressing **the Knob**. The option is then displayed in blue, as shown in Fig.13-6.

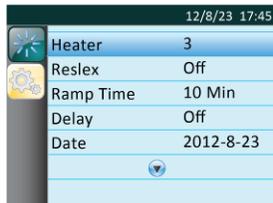


Fig. 13-6

13.1.7 Turning Pages

When the cursor is on **Date**, the last option shown in Fig.13-6, the remaining options will appear on a new page if you continue to turn **the Knob** clockwise, as shown in Fig.13-7.



Fig. 13-7

Note: ⬆️⬆️ are page turning symbols.

13.1.8 Exiting the Patient Menu

(1) Returning to the Initial Setup Interface

Move the cursor to the **Back** option by turning **the Knob**, as shown in Fig.13-8.

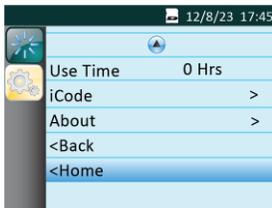


Fig. 13-8

Press **the Knob**, the cursor jumps to the second icon  on the left side of the screen. The screen displays the Initial Setup Interface, as shown in Fig.13-9.



Fig. 13-9

(2) Returning to the Main Interface

Move the cursor to the **Home** option by turning **the Knob**, as shown in Fig.13-10.

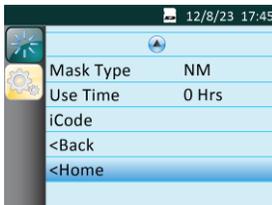


Fig. 13-10

Press **the Knob** to exit the Patient Menu. The screen will display the Main Interface shown in Fig.13-1

13.2 Options of the Patient Menu and Corresponding Descriptions

Option	Range	Description
Heater	Off, 1-5	There are five humidity levels available. As the numbering increases, the humidity rises accordingly. "Off" means the humidifier is turned off. The default setting is "2."
RESlex	Off, 1-3	This feature enables the device to automatically reduce the treatment pressure when the patient exhales, so as to make the user more comfortable. The higher the numbering is, the more pressure the device reduces. "Off" means this feature is disabled. The default setting is "Off."
Ramp Time	0-Ramp Max	In order to increase comfort and help the patient fall asleep easily, the pressure can increase gradually, when the Ramp feature is enabled. The ramp time during which the initial pressure rises to the prescribed treatment pressure can be adjusted. As you turn the Knob to the nearest point, the numbering increases or decreases by five minutes. The default setting is " 10 minutes ." The screen displays a real-time countdown of the remaining ramp time in minutes.
Delay	On/Off	When the humidifier is on, this feature allows the airflow to continue for about 15 minutes at a low pressure (about 2 hPa) after you press the Knob to discontinue treatment. This will blow off the vapor left in the humidifier to avoid any damage to the device. When this feature is set to "Off," which means it is disabled, the airflow stops instantly after you press the Knob . The default setting is "Off."
Date	2000-01-01 — 2099-12-31	Setting date by adjusting this option.
Time	—	Setting time by adjusting this option.
Brightness	High/Low	Setting screen brightness by adjusting this option. The default setting is " High ."
Mask Type	FM; NM; PM; A, B, C	There are three mask types available, namely FM (full-face mask), NM (nasal mask), and PM (nasal pillow mask). The default mask type is " NM ," but the patient can choose other suitable masks as well. When selecting masks other than the above three types of BMC masks, the patient can identify the masks as A, B, or C.
Use Time	0-50000 Hrs	Use Time displays how long has the device been used by the user. The use time can be erased.
iCode	iCode I, iCode II	iCode provides access to the patient's compliance data during a recent time period. The iCode I mode displays data in sequences of characters, and the iCode II mode displays data in two-dimensional codes.

14. Alert

Alert Message	Description
Loss of Power!!!	An audible alert will sound if the device is accidentally disconnected from power when it is delivering air. Note: (1) The alert will not sound if power failure occurs when the device is in standby state. (2) No alert message on the screen during a power failure.
Ventilator Inoperative!!!	An audible alert will sound if no airflow comes out of the machine; the screen will display " Ventilator Inoperative!!! "
Leak!!	When the airflow is on, an audible alert will sound if the air leak rate exceeds 150 l/min; the screen will display " Leak!! "
Low Input Voltage!!	If you use a battery rather than an external power adapter to power the device, an audible alert will sound when the battery is low; the screen will display " Low Input Voltage!! "
Humidifier Failure!!	when humidifier is applied, an audible alert will sound when the humidifier fails to work; the screen will display " Humidifier Failure!! "
Please Replace Filter!	When the Filter Alert feature is enabled, an audible alert will sound if an air filter has been used for more than six months; the screen will display " Please Replace Filter! "
SD Card Full!	The screen will display " SD Card Full! " if the SD card has reached its maximum capacity.
Remove and Reinsert!	The screen will display " Remove and Reinsert! " if the SD card fails to work.

15. Cleaning and Disinfection

WARNINGS!

- Regular cleaning of the device and its accessories is very important for the prevention of respiratory infections.
- To avoid electric shock, always unplug the device before cleaning.
- Use washing liquid that is nontoxic to humans and does not cause allergies in humans.
- Follow the manufacturer's instructions on cleaning the mask and tube and on determining the frequency of cleaning.
- Before cleaning, check whether the device has been disconnected from the power supply, whether the power cord has been unplugged, and whether the water chamber of the humidifier has cooled down. Make sure the heater plate has cooled down to room temperature, so you do not get burned.

CAUTIONS!

- Overheating of the materials could lead to early fatigue of these materials.
- Do not use solutions containing chlorinated lime, chlorine, or aromatic to clean the device and its accessories. Liquid soap containing the humidifying agent or antimicrobials should not be used either. These solutions may harden cleaned materials or reduce their life.
- Do not clean or dry the device and its accessories when the temperature is higher than 80°C (176°F). High temperatures could reduce product life.
- Do not immerse the device in any fluids.

15.1 Cleaning the Mask and Headgear

For details, refer to the cleaning instructions in the user manual for the mask.

15.2 Cleaning the Water Chamber of the Humidifier

For details, refer to the cleaning instructions in the user manual for the humidifier.

15.3 Cleaning the Enclosure

Wipe the surface of the device with a soft, slightly damp cloth.

CAUTION!

- The device can only be used after the enclosure is dry, so that no moisture enters the device.

15.4 Cleaning the Tube

- (1) Remove the tube from the device and mask before cleaning.
- (2) Clean the tube in warm water which contains washing liquid, and then rinse it in clean water thoroughly.
- (3) After cleaning, air-dry the tube in a cool, well-ventilated area, and avoid direct sunlight. It takes approximately 30 minutes to completely air-dry the tube. Check whether the tube is

completely dry before re-use.

15.5 Replacing the Air Filter

- (1) Open the air filter cap to remove the air filter.
- (2) Put the new air filter in the filter area, and then place the filter cap back properly.

CAUTIONS!

- To avoid material damage, do not place the spare air filter in direct sunlight, humid environments, or temperatures below the freezing point. The air filter should be replaced every 6 months (It may be replaced more frequently based on actual sanitary conditions).
- Operating the device with a dirty air filter may stop it from working properly and may cause damage to the device.
- Replacing the air filter and filter cap, device must be unplugged.

15.6 Disinfection

Generally speaking, if you have strictly followed the above cleaning instructions, you do not have to disinfect the device and/or humidifier. If the device is contaminated or used in clinical trials, you may purchase disinfectants from a pharmacist to disinfect the water chamber.

See the Disinfection section of the humidifier user manual for more information on the disinfection of the water chamber.

CAUTIONS!

- Disinfectants tend to damage materials and reduce the life of components. Try to select the appropriate disinfectant, and follow the disinfectant manufacturer's instructions and recommendations.
- After disinfection, check the disinfected component for any signs of damage. Replace any damaged component immediately.

WARNINGS!

- After disinfection, rinse any disinfected component in clean water thoroughly, especially components in close contact with the patient such as the mask, headgear, and tube, so as to prevent disinfectant residuals from damaging the skin or respiratory tract or causing allergies.
- The device shall not be serviced or maintained while in use with a patient.
- Sterilization of this device and its components other than recommended is not permitted.

16. Traveling with the Device

CAUTIONS!

- Empty the water chamber of the humidifier before packing the device for your trip; in order to prevent any remaining water from entering the device.
- Using the device at an incorrect elevation setting could result in airflow pressures higher than the prescribed setting. Always verify the elevation setting when traveling or relocating.
- If the device is used when the atmospheric pressure is out of the stated range (See Section 5), the accuracy of the leakage alert will be affected.

(1) Use the BMC carrying case to carry the device and accessories along with you. Do not put them in your checked baggage.

(2) This device operates on power supplies of 100-240 V and 50/60 Hz, and is suitable for use in any country in the world. No special adjustment is necessary, but you will need to find out the types of the power sockets in your destination. Bring, if necessary, a power socket adaptor which can be bought in electronics stores.

(3) Remember to bring a spare air filter and the emergency documents (filled and signed by your physician) about this device. If you plan to travel by air, remember to bring the multi-language emergency documents about respiratory therapy, in case that the border and customs officers in your destination country inspect the device. With the emergency documents, you can prove to them that it is a medical device.

(4) Security Stations: For convenience at security stations, there is a note on the bottom of the device stating that it is medical equipment. It may be helpful to bring this manual along with you to help security personnel understand the device.

17. Transferring the Device to Another Patient

If the device is transferred to another patient, components in close contact with the previous owner, including the mask, headgear, tube, and air filter, should be cleaned and disinfected to prevent cross-infection.

18. Reordering

Contact your home care provider to order accessories or replacement filters.

The device does not require routine servicing.

WARNINGS!

- If you notice any unexplained changes in the performance of the device, if it is making unusual or harsh sounds, if it has been dropped or mishandled, if the enclosure is broken, or if water has entered the enclosure, discontinue use. Contact your home care provider.
- If the device malfunctions, contact your home care provider immediately. Never attempt to open the enclosure of the device. Repairs and adjustments must be performed by BMC-authorized service personnel only. Unauthorized service could cause injury, invalidate the warranty, or result in costly damage.
- If necessary, contact your local authorized dealer or BMC Medical Co., Ltd. for technical support and documents.

19 Technical Support

Please contact BMC directly if you need the circuit diagram of the device and the list of components for certain purposes such as maintenance or connection to other equipment. BMC will provide the circuit diagram and/or other technical documents in whole or in part according to your needs.

20. Disposal

When the device reaches the end of its service life, dispose of the device and packaging in accordance with local laws and regulations.

21. Troubleshooting

The table below lists common problems you may have with the device and possible solutions to those problems. If none of the corrective actions solve the problem, contact your home care provider.

21.1 Common Problems in Patients and Corresponding Solutions

Problem	Possible Cause	Solution(s)
Dry, cold, runny, and blocked nose; having a cold	The nose reacts to the airflow and cold. Due to fast airflow, the air becomes cold, leading to nasal mucosa irritation and subsequent dryness and swelling.	Increase the humidity setting of the humidifier. Contact your physician, and continue treatment unless the physician suggests the opposite.
Dry mouth and throat	Probably because the patient sleeps with his or her mouth open, and the pressurized air goes out via the mouth, leading to nasal and throat dryness.	Use a chin strap to prevent the mouth from opening during sleep, or use a full-face mask. Contact your physician for details.
Eye irritation	The mask size or model may not be correct, or the mask is not positioned correctly, thereby leading to air leakage.	Narrow the distance between the forehead support of the mask and the forehead. Note that adjusting the mask too tight may leave markings on the patient's face. Add additional filling to the mask so it does not leak. Contact your equipment supplier for an appropriate mask. Add additional filling to the mask if necessary.
	Mask cushion (the soft part of the mask) hardens.	Replace the mask or mask cushion.
Facial reddening	The mask is too tight.	Loosen the headgear.
	The distance between the forehead support of the mask and the forehead is not correct.	Try a different distance. The angle and size of the forehead support differ according to the type of masks.
	Wrong mask size	Contact your equipment supplier for a correct-size mask.

	The patient is allergic to the materials of the mask.	Contact your physician and equipment supplier. Use a latex-free mask. Place a lining between the skin and mask.
Water in mask	When the humidifier is used, the humidified air tends to condense in the cold tube and mask if the room temperature is low.	Turn the humidity setting down, or raise the room temperature. Place the tube under the quilt, or use the tube cover. Hang the tube loosely, and the lowest part of the tube should be lower than the patient's head.
Nasal, sinus, or ear pain	Sinus or middle ear inflammation	Contact your physician immediately.
Discomfort due to inability to adapt to the treatment pressure	The patient will feel uncomfortable when the treatment pressure is higher than 13 hPa. However, the treatment pressure is determined according to the patient's conditions, and cannot treat sleep apnea if the treatment pressure is set too low.	It takes a maximum of four weeks to adapt to pressurized air. Relax and breathe through the nose. If the problem still exists, contact your physician.
Obstructive sleep apnea symptoms recur.	Probably because the patient sleeps with his or her mouth open, and the pressurized air goes out via the mouth, leading to blockage in the respiratory tract.	Use a chin strap to prevent the mouth from opening during sleep, or use a full-face mask. Contact your physician for details.
The device is too noisy.	The tube is not connected properly.	Reconnect the tube properly.
Air delivered from the device is abnormally hot.	The air inlet of the device may be partially blocked, leading to insufficient airflow into the device.	Replace the air filter (see 15.5 Replacing the Air Filter), and clean the air inlet. Place the device in an area where air flows freely, and make sure the device is at least 20 centimeters away from the wall, curtain, or other things.

21.2 Common Problems in the Device and Corresponding Solutions

Problem	Possible Cause	Solution(s)
The device does not work when it is turned on.	The Auto On/Off feature is enabled	Take a few deep breaths with the mask on, and the device will start automatically.
	Power is not connected properly.	Ensure that the power cord, power adapter, and the device are connected properly.
	There is no voltage.	Check whether a power outage occurs by turning on a light or other means. If you are sure the fuse in the device is broken, contact your equipment supplier for repair.
	Cannot find any cause.	Contact your equipment supplier.
The device is working, but the pressure inside the mask differs from the set treatment pressure.	The tube is not connected properly.	Reconnect the tube properly.
	There may be holes in the mask or pressure sensing tube.	Contact your equipment supplier.
	It is a faulty device.	Contact your equipment supplier.
The device produces very low pressures.	The air inlet of the device may be blocked.	Replace the air filter (see 15.5 Replacing the Air Filter), and clean the air inlet. Make sure the air inlet is unblocked.
	The treatment pressure has been changed accidentally.	Contact your physician.
	When the Ramp feature is enabled, it takes some time for the initial pressure to rise to the treatment pressure. This is normal.	If necessary, disable the Ramp feature, or set the ramp time shorter.
After the device is turned on, the screen displays intermittently, or displays nothing at all.	The operating system of the device needs to be readjusted or restarted.	Unplug the power cord of the device, and re-plug it 20 seconds later.
The device is in standby, and will not start.	The operating system of the device needs to be readjusted or restarted.	Unplug the power cord of the device, and re-plug it 20 seconds later.

22. EMC Requirements

Guidance and manufacturer's declaration - electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The user of the device should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical home or hospital.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical home or hospital.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or from a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	If the pressure deviates more than is indicated in the device specifications, it may be necessary to position the device further from sources of power frequency magnetic fields. The power frequency magnetic field should be measured in the intended installation location to ensure that it is sufficiently low.
Note: U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 Vrms</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d=1.2\sqrt{P}$ $d=1.2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d=2.3\sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>Note 1: At 80 MHz and 800 MHz, the higher frequency range applied.</p> <p>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

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

Recommended separation distances between portable and mobile RF communications equipment and the device

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

Rated maximum output of transmitter W	150kHz~80MHz $d=1.2\sqrt{P}$	80MHz~800 MHz $d=1.2\sqrt{P}$	800 MHz~2.5GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

23. Limited Warranty

3B Medical, Inc.(hereafter '3B') warrants that the RESmart® CPAP and Auto-CPAP devices will be free of all defects in workmanship and materials, and will perform according to specifications, for a period of two (2) years from the date of sale of the device, and 90 days on any accessories.

If the product fails to perform in accordance with the product specifications, 3B will repair or replace at its option, the defective material or part. This warranty *does not* cover damage caused by accident, misuse, abuse, alteration and other defects not related to material or workmanship.

- 3B will issue an RMA (Return Merchandise Authorization) within 24 hours of receipt of written notification of a failed or defective unit. Failed/defective units must be returned within 30 days of the RMA date.
- Shipping the machine to us for warranty diagnostic is the customer's responsibility. Warranty covers Domestic Shipping back to you. Please contact us for all warranty claims or questions.
- This warranty coverage is applicable to all 3B/BMC CPAP, Auto CPAP and Auto Bi-level devices.
- The warranty policy *does not* cover any damages caused as a result of alteration, intentional damage, modification, or unauthorized repair of the device.
- Warranty *does* include reasonable water damage and is at the sole discretion of 3B.
- This warranty replaces all other expressed or implied warranties, including any implied warranty of merchantability or fitness for a particular purpose. 3B reserves the right to amend this policy at any time.

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3B™

H60 Heated Humidifier

User Manual



CE 0123

The H60 Heated Humidifier is designed only for use with specific RESmart GII E-20A and E-20C Series devices. Do not use the H60 Heated Humidifier with any other devices.

The humidifier moistens the air delivered by the RESmart GII E-20A and E-20C Series devices. It is for use in the home or hospital/ institutional environment.

The H60 Heated Humidifier is only used for single patient and must not be re-used on another person. This is to avoid the risk of cross-infection.

The H60 Heated Humidifier is not intended for use with a patient whose upper airway has been bypassed.

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1. Warning, Caution and Important Tip

WARNING!

Indicate the possibility of injury to the user or operator.

CAUTION!

Indicate the possibility of damage to the device.

IMPORTANT TIP!

Place emphasis on an operating characteristic.

Warnings, Cautions, and Important Tips appear throughout this manual as they apply.

2. Symbols

-  Operating Instructions
-  Type BF Applied Part
-  Class II (Double Insulated)
-  AC Power
-  DC Power
- IP22** ≥ 12.5 mm Diameter, Dripping (15° tilted)
-  Hot Surface
-  Serial Number of the Product
-  Manufacturer
-  Authorized Representative in the European Community
-  European CE Declaration of Conformity
-  Water Filling Prohibited Here
-  Water Inlet
-  Directional Indicator for Removing the Water Inlet Cap
-  Directional Indicator for Screwing the Water Inlet Cap

3. Features

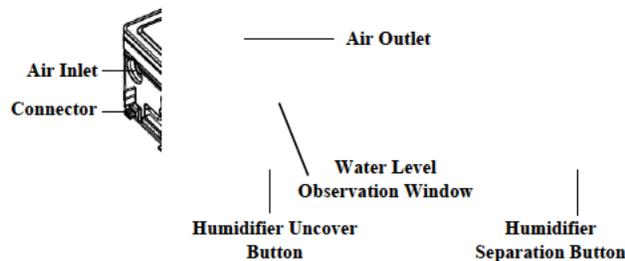


Fig. 3-1

Name	Function
Air Inlet	Connect to the outlet of the main device
Air Outlet	Deliver humidified air to the patient; connect to the air tubing
Connector	Heat the water in the water chamber and detect the temperature
Water Level Observation Window	Observe the water level in the water chamber
Humidifier Uncover Button	Press this button to open the top cover of the humidifier

Humidifier Separation Button	Press this button to separate the humidifier from the main device
------------------------------	---

4. Daily Use

IMPORTANT!

- Never operate the humidifier if any of its parts are damaged, if it is not working properly, or if the humidifier has been dropped or mishandled. Do not use the humidifier if the water chamber is leaking or damaged in any way. Have any damaged parts replaced before continuing use.
- Read all instructions before using the humidifier.
- Use only with BMC devices whose instructions specify the use of this humidifier.

CAUTIONS!

- This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- Do not operate the device in direct sunlight or near a heating appliance because these conditions can increase the temperature of the air coming out of the device.
- When humidifier is used outside the specified ambient temperature range or humidity range, the performance of humidifier will be compromised.
- U.S. federal law restricts this device to sale by or on the order of a physician.

WARNINGS!

- Use the humidifier only for its intended use as described in this manual.
- Use only accessories recommended by BMC.

4.1 Connecting, Separating the Humidifier and Main Device

4.1.1 Connecting the Humidifier to the Main Device

Remove the shield from the main device, following the steps below:

- (1) Overturn the main device and find the buckle slot at the bottom of the main device, as shown in Fig.4-1.
- (2) Remove the shield by inserting a flat tool into the buckle slot.

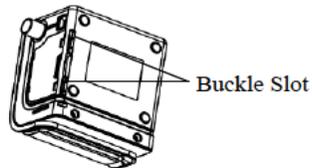


Fig. 4-1

After the shield is removed, place the humidifier and main device near each other as shown in Fig.4-2. The air outlet of the main device should be targeted to the inlet of the humidifier. Push the two devices together until they click into place. Fig.4-2 shows their positions before and after connection to each other.

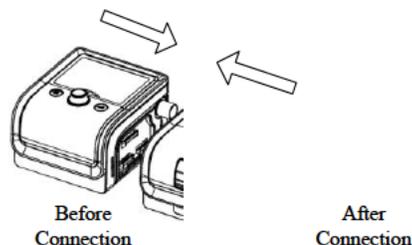


Fig. 4-2

CAUTION!

- When the main device delivers air and the humidity setting is adjusted, if the indicator lights of the humidifier do not light up, it may be that the humidifier and main device are not connected correctly.

4.1.2 Separating the Humidifier from the Main Device

Press the **Humidifier Separation Button** on the humidifier and, at the same time, pull the humidifier and main device apart in opposite horizontal directions, as shown in Fig.4-3.

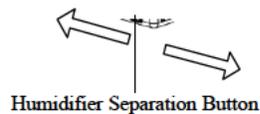


Fig. 4-3

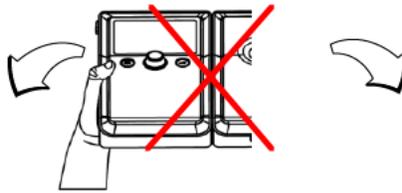


Fig. 4-4

CAUTIONS!

- Do not move the connected unit upwards or downwards while pulling the devices apart (see Fig.4-4). It could cause damage to the devices.
- Place the shield back on the main device when the humidifier is not in use.

4.2 Filling the Water Chamber**4.2.1 Removing the Water Chamber**

Press the **Humidifier Uncover Button** to open the top cover. Hold the front center of the humidifier with your thumb and index finger, and pull the chamber out of the humidifier, as shown in the figure below.

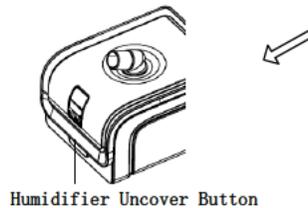


Fig. 4-5

WARNING!

- Turn the device off and allow approximately 15 minutes for the heater plate and water to cool.

4.2.2 Overturning the Water Chamber

Turn the water chamber over so that it is bottom up, as shown in the figure below.

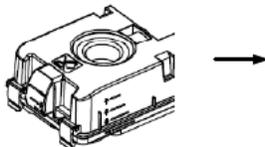


Fig. 4-6

WARNINGS!

- Never touch the heater plate unless the humidifier is unplugged and the plate has cooled down.
- Fill the water chamber only after it is turned over, otherwise the device could be damaged.

4.2.3 Removing the Water Inlet Cap

Turn the water inlet cap counterclockwise so the arrowhead on the cap points to the triangle symbol \triangle , and then remove the cap.



Fig. 4-7

4.2.4 Filling Water

Fill the water chamber with approximately 350 ml of water through the water inlet. Make sure that the water does not exceed the maximum water level line. Observe the water level in the water chamber through the Water Level Observation Window.

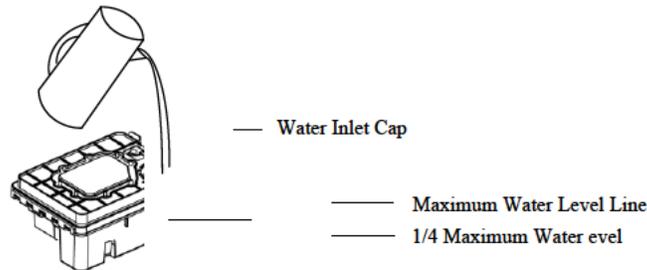


Fig. 4-8

WARNING!

- Every time before treatment, be sure to drain any residual water out of the water chamber, and ensure the maximum water level line is not submerged by water.

CAUTIONS!

- Empty the water chamber when the humidifier is not in use.
- Distilled water is recommended.

4.2.5 Returning the Water Chamber

Put the cap back on the water chamber after it is filled with water. Turn the cap clockwise until the arrowhead on the cap points to the round symbol . Overturn the water chamber and return it to the humidifier.

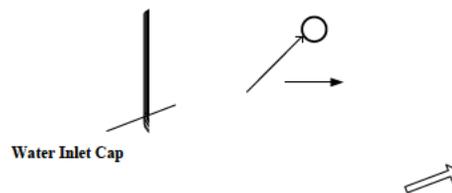


Fig. 4-9

WARNING!

- For safety purposes, the filled humidifier must be placed on a flat surface at a level lower than the patient's head when he or she lies down on a bed, so that the condensation flows back to the water chamber rather than remain in the tubing inhibiting breathing.

CAUTIONS!

- Avoid moving or tilting the humidifier when the water chamber has water in it.
- Do not turn the humidifier on without the water chamber installed.
- Take precautions to protect furniture from water damage.

4.3 Emptying the Water Chamber

(1) Remove the water chamber according to instructions in 4.2.1.

(2) **Empty the water chamber:** Separate the main body of the water chamber from the chamber base, and pour any remaining water out of the main body of the water chamber. Undo the **Water Chamber Buckle**, and open the water chamber as shown below.

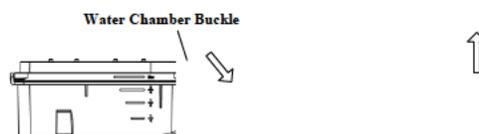


Fig. 4-10

CAUTION!

- Empty and air-dry the water chamber when the humidifier is not in use.

(3) Assemble the water chamber: Place the main body of the water chamber on a level surface, and then insert the chamber base into the main body of the water chamber and fasten the **Water Chamber Buckle**, as shown in the figure below.

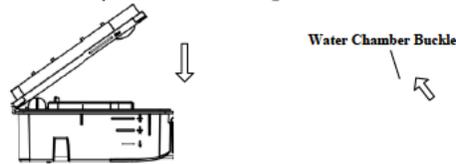


Fig.4-11

4.4 Setting the Humidity Level

After the main device is powered on, turn the **knob** to turn on or turn off the humidifier and to adjust the humidity level according to instructions on the screen of the main device.

There are five humidity levels available, and the number of blue indicator lights that light up is directly proportional to the humidity level. If none of the indicator lights light up, it means that the humidifier is turned off.

The temperature of the water in the water chamber maintains a constant set level. Three indicator lights light up when the humidity is adjusted to Level 3, as shown in Fig.4-10.



Fig. 4-12

CAUTIONS!

- Generally speaking, the humidity inside the mask is low when the water temperature is low.
- The greater the difference between the temperature inside the air tubing and room temperature is, the more easily condensation occurs inside the tubing.
- If there are only a few condensed water droplets inside the tubing in the morning after therapy, it means that the humidity level is proper; if there are lots of condensed water droplets inside the tubing and/or mask, it means that the humidity level is too high and should be set lower; Nasal dryness means that the humidity level is too low and should be set higher.

WARNING!

- Do not touch the heater plate of the humidifier when it is working, otherwise you may get burned. Turn off the heater plate when the humidifier is not in use.

5. Cleaning

Clean the water chamber before first use of the humidifier or at least once every week. If the humidifier has not been in use for a long time, clean the water chamber before reusing it.

WARNING!

- To avoid electrical shock, disconnect the power cord of the device before cleaning the humidifier. DO NOT immerse the humidifier in any fluids.

CAUTIONS!

- Do not use solutions containing chlorinated lime, chlorine, or aromatic to clean the device and its accessories. Liquid soap containing the humidifying agent or antimicrobials should not be used in cleaning either. These solutions may harden cleaned materials or reduce their life.
- Do not clean or dry the device and its accessories when the temperature is higher than 80°C(176°F). High temperatures could reduce product life.

5.1 Separating the Humidifier Top Cover from its Main Body

Press the **Humidifier Uncover Button** to lift and open the top cover of the humidifier. Continue to lift the top cover until it separates completely from the main body of the humidifier, as shown in the figure below.

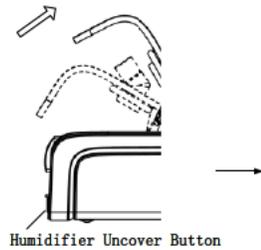


Fig. 5-1

5.2 Removing the Water Chamber

Pull the water chamber out of the main body of the humidifier horizontally, as shown in the figure below.

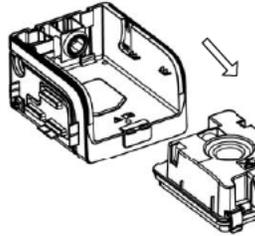


Fig. 5-2

5.3 Detaching the Air-intake Assembly

After the water chamber is removed, detach the **air-intake assembly** from the main body of the humidifier by pulling it upwards, as shown in the figure below.

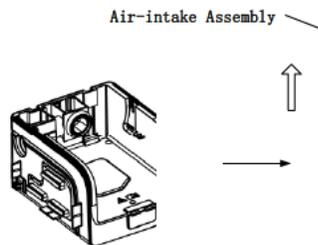


Fig. 5-3

5.4 Cleaning the Water Chamber

WARNINGS!

- Emptying and cleaning the water chamber daily will help prevent mold and bacteria growth.
- Allow the water in the chamber to cool down to room temperature before removing it from the humidifier.

CAUTIONS!

- Clean the water chamber only after the water in it cools. Make sure that no water enters the main device.
- After cleaning, rinse all parts thoroughly in clean water to make sure that no washing liquid is left; then wipe all parts dry with a lint-free cloth, so as to prevent calcareous accumulations.
- Inspect the water chamber for any leak or damage. Replace the water chamber if any damage is present.

(1) Opening the Water Chamber: Undo the **water chamber buckle** and then open the water chamber.

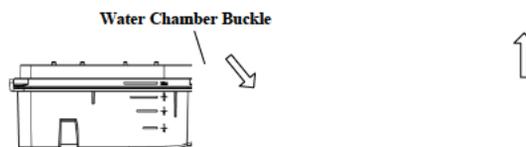


Fig. 5-4

(2) Cleaning the Water Chamber: Wash the two parts of the water chamber, as shown in Fig.5-2. You may also clean them with a scouring pad (dip the scouring pad in washing liquid if necessary), rinse them thoroughly, and then wipe them dry with a soft cloth.

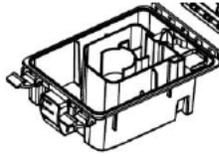


Fig. 5-5

(3) Assembling the Water Chamber: Place the two parts of the water chamber together as shown in Fig.5-6. Press hard until they click into place.

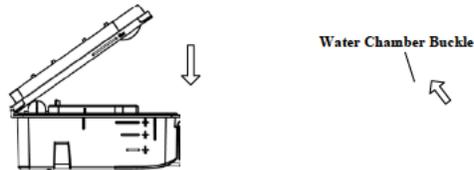


Fig. 5-6

5.5 Cleaning the Air-intake Assembly

First remove the sealing elements from the air-intake assembly, and then clean the air intake and sealing elements separately with running water, as shown in the figure below. They can also be cleaned with a scouring pad (dip the pad in mild scrubbing solutions if necessary), and then rinsed thoroughly. Wipe the air intake with soft cloth, and allow the sealing elements to air dry.

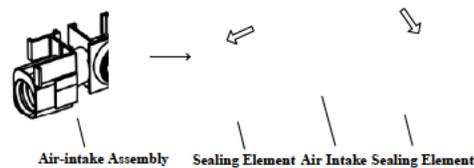


Fig. 5-7

5.6 Cleaning the top cover and main body of the humidifier

Clean the top cover and main body of the humidifier separately with running water, as shown in the figure below. They can also be cleaned with a scouring pad (dip the pad in mild scrubbing solutions if necessary), then rinsed thoroughly, and at last wiped with soft cloth.

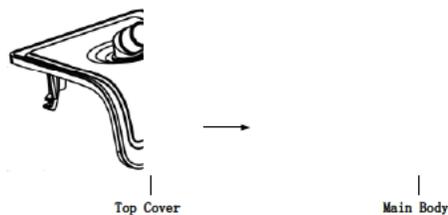


Fig. 5-8

5.7 Reassembling the Humidifier

(1) Set up the air-intake assembly: First install the sealing elements to the air intake, as shown in the figure below.

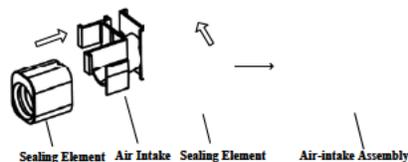


Fig. 5-9

(2) Then install the air-intake assembly back to the main body of the humidifier, as shown in the figure below.

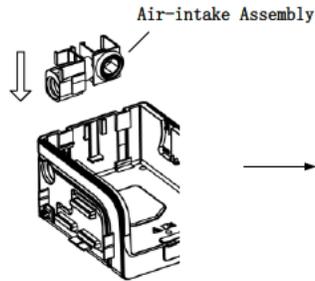


Fig. 5-10

(3) Return the water chamber to the main body of the humidifier, as shown in the figure below.

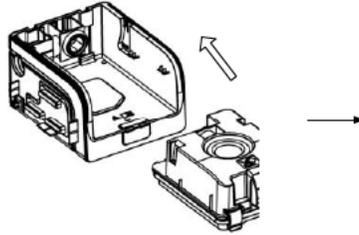


Fig. 5-11

(4) Connect the top cover and main body of the humidifier properly, as shown in the figure below.

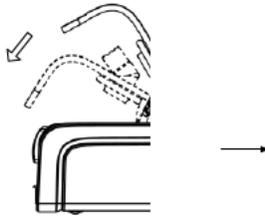


Fig. 5-12

6. Disinfection

Generally speaking, if you have strictly followed the above cleaning instructions, you do not have to disinfect the humidifier. If the device is contaminated or used in clinical trials, you may purchase disinfectants from a pharmacist to disinfect the water chamber.

Disinfection of Humidifier Water Chamber

Prior to disinfection, clean the water chamber according to Section 5.4 "Cleaning the Water Chamber." The disinfection methods are as follows:

- (1) Heat disinfection: Disinfect the water chamber by immersing it in tap water at $75^{\circ}\text{C}\pm 2^{\circ}\text{C}$ for 30 minutes.
- (2) Use mild disinfectants.

CAUTIONS!

- Disinfectants tend to damage materials and reduce the life of components. Try to select the appropriate disinfectant, and follow the disinfectant manufacturer's instructions and recommendations.
- After disinfection, check the disinfected component for any signs of damage. Replace any damaged component immediately.

WARNINGS!

- After disinfection, rinse any disinfected component in clean water thoroughly, especially components in close contact with the patient such as the mask, headgear, and tube, so as to prevent disinfectant residuals from damaging the skin or respiratory tract or causing allergies.
- The device shall not be serviced or maintained while in use with a patient.
- Sterilization of this device and its components other than recommended is not permitted.

7. Service

The humidifier does not require routine servicing.

If the humidifier malfunctions, contact your home care provider immediately. Never attempt to open the humidifier's enclosure. If necessary, contact your local authorized dealer or BMC Medical Co., Ltd. for technical support and documents.

8. Specifications

Size

Dimensions: 120 × 196 × 134 mm

Weight: < 1 kg

Water Capacity: 350 ml at recommended water level

Product Use, Transport and Storage

	Operation	Transport and Storage
Temperature:	5 to 35°C (41°F to 95°F)	-20 to 55°C (-4°F to 131°F)
Humidity:	15 to 93% Non-condensing	15 to ≤ 93% Non-condensing
Atmospheric Pressure:	760 to 1060 hPa	760 to 1060 hPa

Power Requirements (when the heated humidifier is used with the main device.)

100–240 V AC, 50/60 Hz, 2.0 A max.

Type of Protection Against Electric Shock

Class II Equipment

Degree of Protection Against Electric Shock

Type BF Applied Part

Degree of Protection Against Ingress of Water

IP22

Heater Settings

1 to 5 (95 to 167°F / 35 to 75°C)

Maximum Operating Pressure

30 hPa

Pressure Drop with Humidifier

<0.4 hPa at 60 LPM flow

Humidifier Performance

Humidity Output: No less than 10 mg H₂O / L

Environmental Conditions: Maximum airflow, 35°C, 15% relative humidity

Maximum Delivered Gas Temperature

<43°C

The Form and the Dimensions of the Patient Connection Port

The 22 mm conical air outlet complies with ISO 5356-1

9. Disposal

When necessary, dispose of the device and accessories in accordance with local laws and regulations.

10. Traveling With the System

Packing the System

- (1) Remove the water chamber and pour out all water.
- (2) Return the empty water chamber to the humidifier.
- (3) Put the humidifier in your carry-on bag.

When traveling, the optional carrying case is for carry-on luggage only. The carrying case will not protect the humidifier if it is put through checked baggage.

Security Stations

For ease at security stations, there is a note on the bottom of the humidifier stating that it is medical equipment. It may be helpful to bring this manual along with you for security personnel.

11. EMC Requirements

Guidance and manufacturer's declaration - electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The user of the device should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical home or hospital.

Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical home or hospital.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or from a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	If the pressure deviates more than is indicated in the device specification, it may be necessary to position the device further from sources of power frequency magnetic fields. The power frequency magnetic field should be measured in the intended installation location to ensure that it is sufficiently low.
Note: U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
Note 1: At 80 MHz and 800 MHz, the higher frequency range applied. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.			
^b Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.			

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

Rated maximum output of transmitter W	150kHz~80MHz $d=1.2\sqrt{P}$	80MHz~800 MHz $d=1.2\sqrt{P}$	800 MHz~2.5GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

12. Warranty

3B Medical, Inc.(hereafter '3B') warrants that this humidifier shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of one (1) year from the date of sale by 3B to the dealer.

If the product fails to perform in accordance with the product specifications, 3B will repair or replace, at its option, the defective material or part. 3B will pay customary freight charges from 3B to the dealer location only. This warranty does not cover damage caused by accident, misuse, abuse, alteration and other defects not related to material or workmanship.

To exercise your rights under this warranty, contact your local, authorized dealers or:

3B Medical, Inc.
21301 US Highway 27N
Lake Wales, FL 33859
T: (863) 226-6285
F: (863) 226-6284

For additional information, please visit our Patient Portal at:
www.3Bproducts.com

Issue date: 24 June, 2014

1、Packaging Label

E-20A-H-O:

AUTO CPAP System	CE ₀₁₂₃
E-20A-H-0	
UNIT SN	E23-----
	
Gross Weight: 5kg	BMC
Dimensions: 335×225×270mm	BMC Medical Co. ,Ltd.
Storage Temp: -25℃~+70℃	5/F Main Building, No.19 Gucheng Street West, Shijingshan, Beijing 100043, P.R.China
Humidity: Up to 93%,non-condensing	

E-20AJ-H-O:

AUTO CPAP System	CE ₀₁₂₃
E-20AJ-H-0	
UNIT SN	E24-----
	
Gross Weight: 5kg	BMC
Dimensions: 335×225×270mm	BMC Medical Co. ,Ltd.
Storage Temp: -25℃~+70℃	5/F Main Building, No.19 Gucheng Street West, Shijingshan, Beijing 100043, P.R.China
Humidity: Up to 93%,non-condensing	

E-20C-H-O:

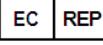
CPAP System		CE ₀₁₂₃
E-20C-H-0		
UNIT SN	E21-----	
		
Gross Weight:	5kg	BMC BMC Medical Co., Ltd. 5/F Main Building, No.19 Gucheng Street West, Shijingshan, Beijing 100043, P.R.China
Dimensions:	335×225×270mm	
Storage Temp:	-25℃~+70℃	
Humidity:	Up to 93%,non-condensing	

2. Drawing of the Label

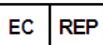
E-20A-H-O:

BMC	AUTO CPAP System	
Model:	E-20A-H-O	IP22
	AC 100-240V, 50/60Hz, Max 2A	
SN	E23-----	
	BMC Medical Co., Ltd.	
	5/F Main Building, No.19 Gucheng Street West, shijingshan, Beijing 100043, PEOPLE'S REPUBLIC OF CHINA	
EC REP	Shanghai International Holding Corp. GmbH (Europe)	CE ₀₁₂₃
	Eiffestraße 80, 20537 Hamburg, GERMANY	

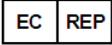
E-20AJ-H-O:

	AUTO CPAP System	
Model:	E-20AJ-H-O	IP22
	AC 100-240V, 50/60Hz, Max 2A	
SN	E24-----	
	BMC Medical Co., Ltd.	
	5/F Main Building, No. 19 Gucheng Street West, Shijingshan, Beijing 100043, PEOPLE'S REPUBLIC OF CHINA	
	Shanghai International Holding Corp. GmbH (Europe)	
	Eiffestraße 80, 20537 Hamburg, GERMANY	0123

E-20C-H-O:

	CPAP System	
Model:	E-20C-H-O	IP22
	AC 100-240V, 50/60Hz, Max 2A	
SN	E21-----	
	BMC Medical Co., Ltd.	
	5/F Main Building, No. 19 Gucheng Street West, Shijingshan, Beijing 100043, PEOPLE'S REPUBLIC OF CHINA	
	Shanghai International Holding Corp. GmbH (Europe)	
	Eiffestraße 80, 20537 Hamburg, GERMANY	0123

H60:

	<h1>Heated Humidifier</h1>
Model:	H60
SN	H21-----
	BMC Medical Co., Ltd. 5/F Main Building, No. 19 Gucheng Street West, Shijingshan, Beijing 100043, PEOPLE'S REPUBLIC OF CHINA
	
	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80, 20537 Hamburg, GERMANY
	

K141770/S001
3B™ Medical, Inc.

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863-226-6285

FAX 863-226-6284

August 21, 2014



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Springs, MD 20993

FDA/CDRH/DCC

AUG 25 2014

RECEIVED

RE: Reply to RTA
SPECIAL 510(K) K141770
RESmart GII CPAP and Auto-CPAP System,
also sold as LUNA CPAP and Auto-CPAP System

Dear Document Control Clerk:

On July 1, 2014, our Special 510(k) was returned with an RTA form outlining deficiencies. Additionally, our Special 510(k) was converted to a Traditional 510(k) based on our declaration to make a change in materials. We have decided not to make a change in any materials, and the proposed device will share identical materials to the declared predicate device. Accordingly, we are asking that this submission revert back to a Special 510(k).

The predicate device for this Special 510(k) is the RESmart CPAP and Auto-CPAP System (K132967). The RESmart CPAP and Auto-CPAP devices proposed herein are being upgraded to include a redesigned enclosure and a larger color LCD with easier to use graphical user interface. Modifications to the product labelling and user manuals includes revisions necessary to conform to the user interface changes.

In response to FDA's RTA notice, the following changes are included in this submission:

3B™ Medical, Inc.

info@3BProducts.com

863-226-6285

FAX 863-226-6284



1. The Description of Design Modifications, Section 8, has been revised to reflect that there are no changes to the Indications for Use.
2. The device labeling has been corrected to properly include "Rx Only".
3. The sections on biocompatibility and substantial equivalence have been corrected to identify that all materials in contact with the air path of the device are identical to the predicate device.
4. The software documents specified by the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices has been appended as Appendix Y

We consider our intent to market this device as confidential commercial information and request that FDA treat it as such. We have taken precautions to protect the confidentiality of the intent to market this device. We understand that submission of false information to the government is prohibited by 18 U.S.C. §1001 and 21 U.S.C. §331(q)

Thank you in advance for your consideration of this application. If you require additional information, please do not hesitate to contact me.

Sincerely

A handwritten signature in black ink, consisting of a series of horizontal and vertical strokes that form a stylized, somewhat abstract representation of the name "Alex Lucio".

Alex Lucio
Vice President

aal/dtg

This eCopy is an exact duplicate of the paper copy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: (b) (4) Write the Payment Identification number on your check.
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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>

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) 3B MEDICAL, INC. 21301 Hwy 27 N Lake Wales USA FL 33859 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****0396	2. CONTACT NAME Alex Lucio 2.1 E-MAIL ADDRESS alucio@3bproducts.com 2.2 TELEPHONE NUMBER (include Area code) 863-2266285 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 863-2266285
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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>)

Select an application type:

<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)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

YES, I meet the small business criteria and have submitted the required qualifying documents to FDA NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number: SBD145281

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?

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.)

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)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

This application is the first PMA submitted by a qualified small business, including any affiliates

The sole purpose of the application is to support conditions of use for a pediatric population

This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE 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

23-Jun-2014

(b) (4)

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August 21, 2014



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Springs, MD 20993

RE: Reply to RTA
SPECIAL 510(K) **K141770**
RESmart GII CPAP and Auto-CPAP System,
also sold as LUNA CPAP and Auto-CPAP System

Dear Document Control Clerk:

On July 1, 2014, our Special 510(k) was returned with an RTA form outlining deficiencies. Additionally, our Special 510(k) was converted to a Traditional 510(k) based on our declaration to make a change in materials. We have decided not to make a change in any materials, and the proposed device will share identical materials to the declared predicate device. Accordingly, we are asking that this submission revert back to a Special 510(k).

The predicate device for this Special 510(k) is the RESmart CPAP and Auto-CPAP System (K132967). The RESmart CPAP and Auto-CPAP devices proposed herein are being upgraded to include a redesigned enclosure and a larger color LCD with easier to use graphical user interface. Modifications to the product labelling and user manuals includes revisions necessary to conform to the user interface changes.

In response to FDA's RTA notice, the following changes are included in this submission:



1. The Description of Design Modifications, Section 8, has been revised to reflect that there are no changes to the Indications for Use.
2. The device labeling has been corrected to properly include "Rx Only".
3. The sections on biocompatibility and substantial equivalence have been corrected to identify that all materials in contact with the air path of the device are identical to the predicate device.
4. The software documents specified by the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices has been appended as Appendix Y

We consider our intent to market this device as confidential commercial information and request that FDA treat it as such. We have taken precautions to protect the confidentiality of the intent to market this device. We understand that submission of false information to the government is prohibited by 18 U.S.C. §1001 and 21 U.S.C. §331(q)

Thank you in advance for your consideration of this application. If you require additional information, please do not hesitate to contact me.

Sincerely

A handwritten signature in black ink, appearing to read "Alex Lucio", written over a horizontal line.

Alex Lucio
Vice President

aal/dtg

This eCopy is an exact duplicate of the paper copy.

Reviewer's Checklist

According to the "Draft DCRND Reviewer's Guidance for Premarket Notifications," November 1993, the following characteristics are identified:

- The RESmart CPAP and Auto CPAP System is not an implantable device.
- The RESmart CPAP and Auto CPAP System is not intended for life support or life sustaining applications.
- The RESmart CPAP and Auto CPAP System is not sold as sterile.
- The RESmart CPAP and Auto CPAP System is not a single-patient-use device.
- The RESmart CPAP and Auto CPAP System must be prescribed by a physician.
- The RESmart CPAP and Auto CPAP System does not contain a drug or biological product as a component.
- The RESmart CPAP and Auto CPAP System is not a kit.
- The RESmart CPAP and Auto CPAP System is software driven.
- The RESmart CPAP and Auto CPAP System is electrically operated.

Indications for Use

510(k) Number:

BMC RESmart® GII (also sold as the Luna) CPAP and Auto-CPAP System

Indications for Use:

The 3B and BMC RESmart® GII (also sold as the Luna) CPAP and Auto-CPAP SystemSystems are intended to deliver positive pressure for the treatment of Obstructive Sleep Apnea. The optional integrated humidifier is indicated for the humidification and warming of air from the flow generator device. These devices are intended for single patient use by prescription in the home or hospital/institutional environment on adult patients.

Prescription Use: X
(Part 21 CFR 801 Subpar D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Device Trade Name CPAP	RESmart® GII (also sold as the Luna) CPAP and Auto- Systems with Integrated Heated Humidifier
Common/Usual Name	CPAP System, Auto-CPAP system
Date Prepared	June 23, 2014
Sponsor Identification	3B Medical, Inc. 21301 Highway 27 N. Lake Wales, FL 33859
Phone	863-226-6285
Fax	863-226-6284
Email	alucio@3bproducts.com
Submission Correspondent	Alex Lucio 3B Medical, Inc. 21301 Highway 27 N. Lake Wales, FL 33859
Phone	863-226-6285
Fax	863-226-6284
Email	alucio@3bproducts.com
Establishment Registration #	3008566132 BMC Medical CO., LTD 5/f Main Building No.19

510(k) Summary

Gucheng Street West, Shinjingshan
Beijing, CHINA 100043

Classification	Class II Device
Classification Panel	Medical Device
Classification Reference	21 CFR 878.5905
Products Code	BZD-Non-continuous Ventilator (Respirator)
Medical Specialties	Anesthesiology
Predicate Device(s)	RESmart® CPAP and Auto-CPAP Systems (K132967)
Reason for Submission:	Device Modification

Intended Use The 3B and BMC RESmart GII CPAP and AutoCPAP Systems are intended to deliver positive pressure for the treatment of Obstructive Sleep Apnea. The optional integrated humidifier is indicated for the humidification and warming of air from the flow generator device. These devices are intended for use by prescription in the home or hospital/institutional environment on adult patients.

Device Description The RESmart GII CPAP and AutoCPAP System is a microprocessor-controlled, blower-based system that generates positive airway pressure from 4 to 20 cm H₂O. The

510(k) Summary

device is intended for use with a patient interface (mask). The device has been modified to include a color LCD, easier to use menu driven user interface, and a redesigned enclosure. The electrical circuit was redesigned to incorporate the color LCD. The basic functionality and performance characteristic of the RESmart CPAP and AutoCPAP GII are unchanged from the predicate device RESmart CPAP and AutoCPAP (K132967).

Non-Clinical Testing

Extensive non-clinical testing was conducted in accordance with IOS 17510-1:2007. , Sleep Apnea Breathing Therapy-Part I: Sleep Apnea Breathing Therapy Equipment. Side by side Performance Bench Testing demonstrated substantial equivalence with the predicated device.

Materials used in the construction of components that contact the heated humidified gas pathway are classified as permanent “external communicating devices” (with tissue/bone/dentin). The appropriate biological tests conducted and passed for these components, in accordance with FDA guidance #G95-1-were:

- ISO 10993-3 Genotoxicity,
- ISO 10993-5 Cytotoxicity
- ISO 10993-6 Implantation and
- ISO 10993-10 Sensitization and Irritation

Testing for particulate matter and volatiles demonstrated compliance to EPA requirements

510(k) Summary

The RESmart GII has been tested to appropriate standards and other applicable requirements. The RESmart GII with integrated heated humidifier was designed and tested according to:

- IEC 60101-1:2005, Medical electrical equipment – Part 1: General Requirements for safety Medical electrical equipment – General requirements for basic safety and essential performance
- IEC 60601-1-2:2007, medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

The proposed and predicated devices have identical materials, indications for use, and operating principles. Testing and validation of component part upgrades establish substantial equivalence between predicate and proposed devices.

Substantial Equivalence The RESmart CPAP and AutoCPAP System (K132967) remain substantially equivalent to the proposed RESmart II CPAP and AutoCPAP/Luna CPAP and AutoCPAP System in that they have the same intended use, same operating principle, same technology, identical materials, and same manufacturing process. Designed validation and verification test were performed on the RESmart® GII (also sold as the Luna) CPAP

510(k) Summary

and Auto-CPAP System because of the risk analysis and product requirements.

Conclusions

There have been no changes in the material composition, intended use, or operating principles. Validation and verification that the proposed device is substantially equivalent to the predicate device.

Premarket Notification and Accuracy Statement

[As required by 21 CFR Sec. 808.87 (k)]

I, Alex Lucio, in my capacity as Vice President of 3B Medical, Inc., believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Dated this 21st day of August, 2014



Alex Lucio

Vice President

3B Medical, Inc.

21301 Highway 27 N

Lakes Wales, FL 33859

Premarket Notification 510(k) 141770

Description of Device Modifications

1 Overview

This Special 510(k) is intended to cover modifications made to the RESmart CPAP and Auto-CPAP (K132967). The modified device, the RESmart GII, is also private labeled as the Luna CPAP and Auto-CPAP.

2 Indications for Use

There are no changes to the Indications for Use from the predicate. The indications for use are:

The 3B and BMC CPAP and Auto CPAP Systems are intended to deliver positive pressure for the treatment of Obstructive Sleep Apnea. The optional integrated humidifier is indicated for the humidification and warming of air from the flow generator. These devices are intended for single patient use by prescription in the home or hospital/institutional environment on adult patients.

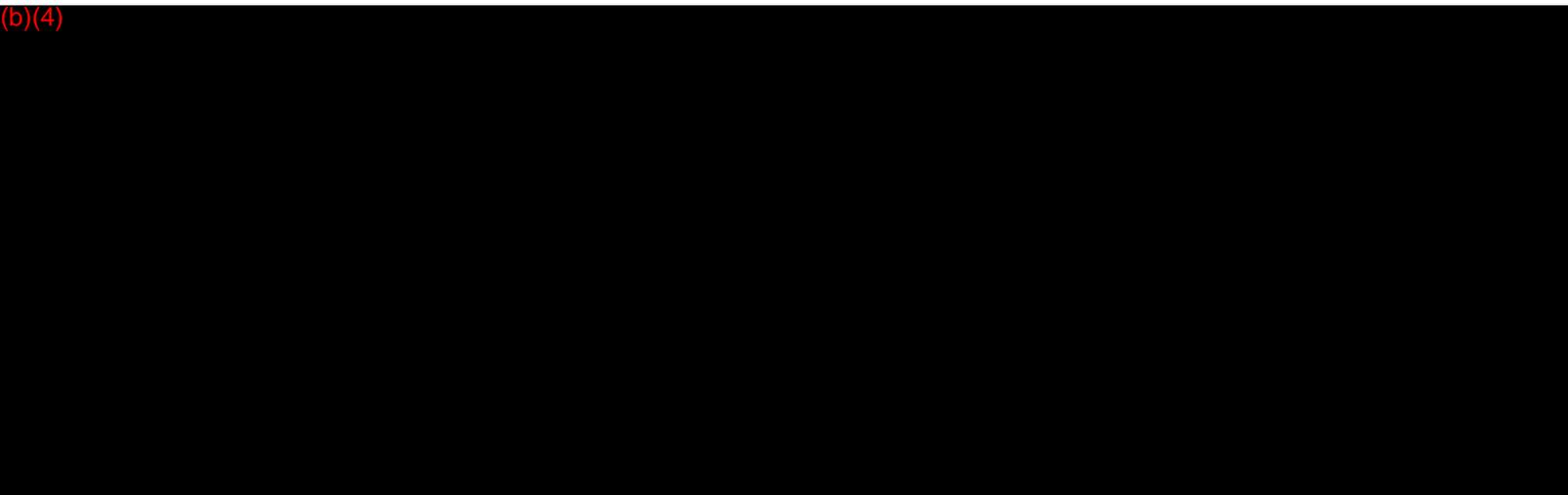
3 Description of Device Modifications

The RESmart GII CPAP and Auto CPAP devices were redesigned to improve the outward aesthetics of the device. The LCD display was changed from monochrome to color with a larger display. The use of a larger color display requires modifications of the user interface to make full use of a larger color display.

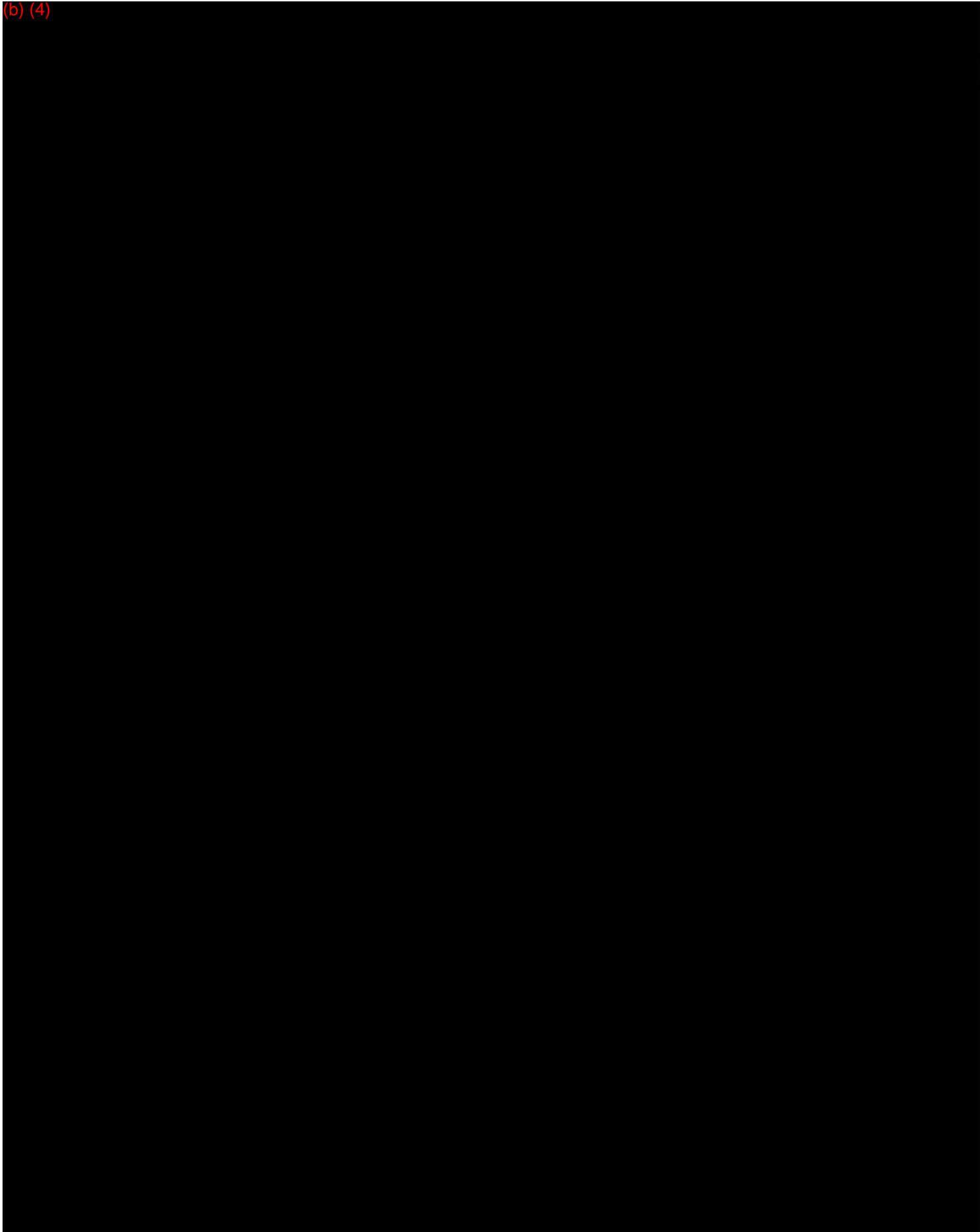
The redesign of the outer shell of the device to improve cosmetic appearance requires some modification of the interior design. The air circuit, embedded software, and controller board have been upgraded to accommodate the UI change and layout redesign. The basic functional and performance characteristics of the CPAP and Auto CPAP devices are unchanged from the predicate devices CPAP and Auto CPAP (K132967).

3.1 Embedded Software

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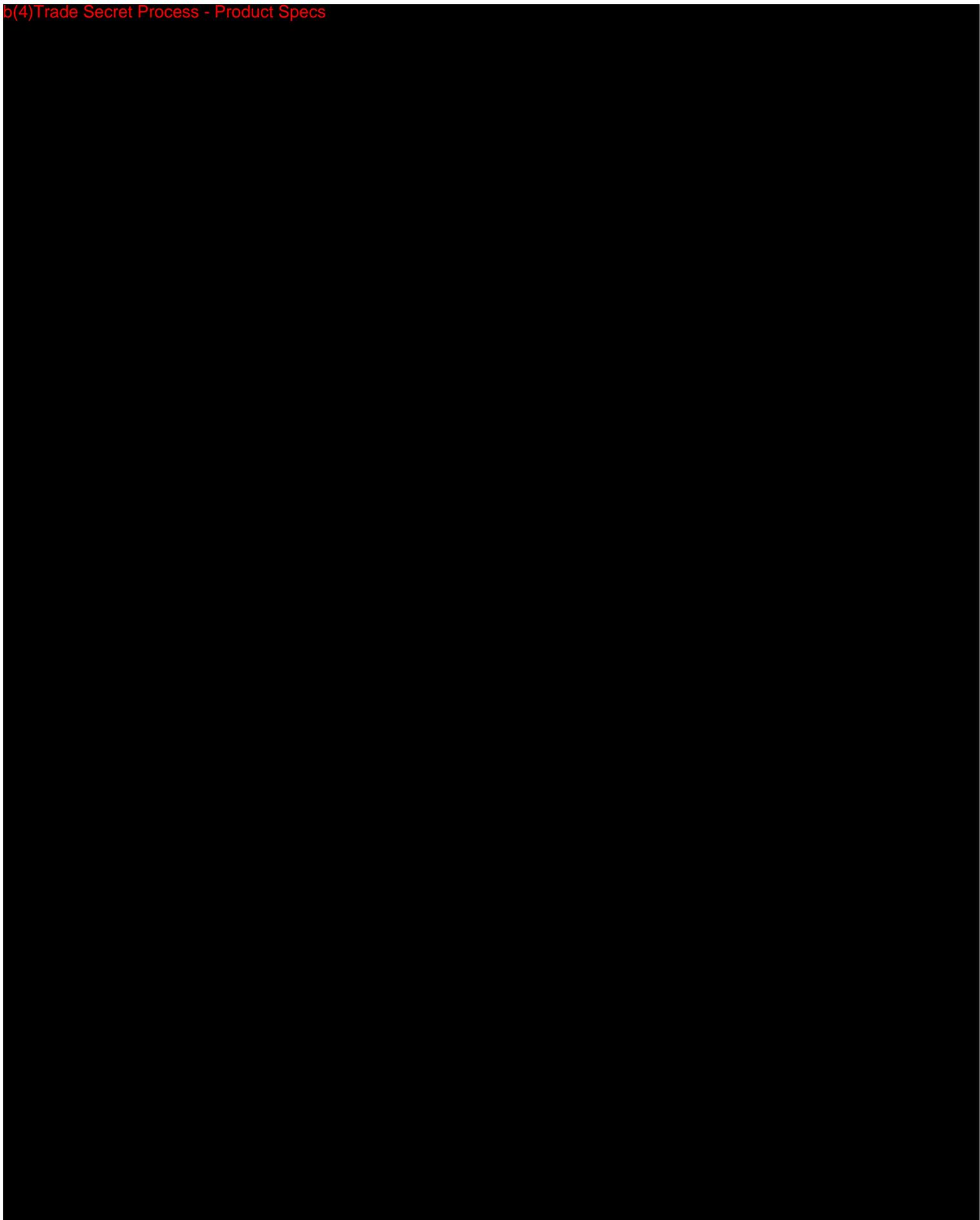


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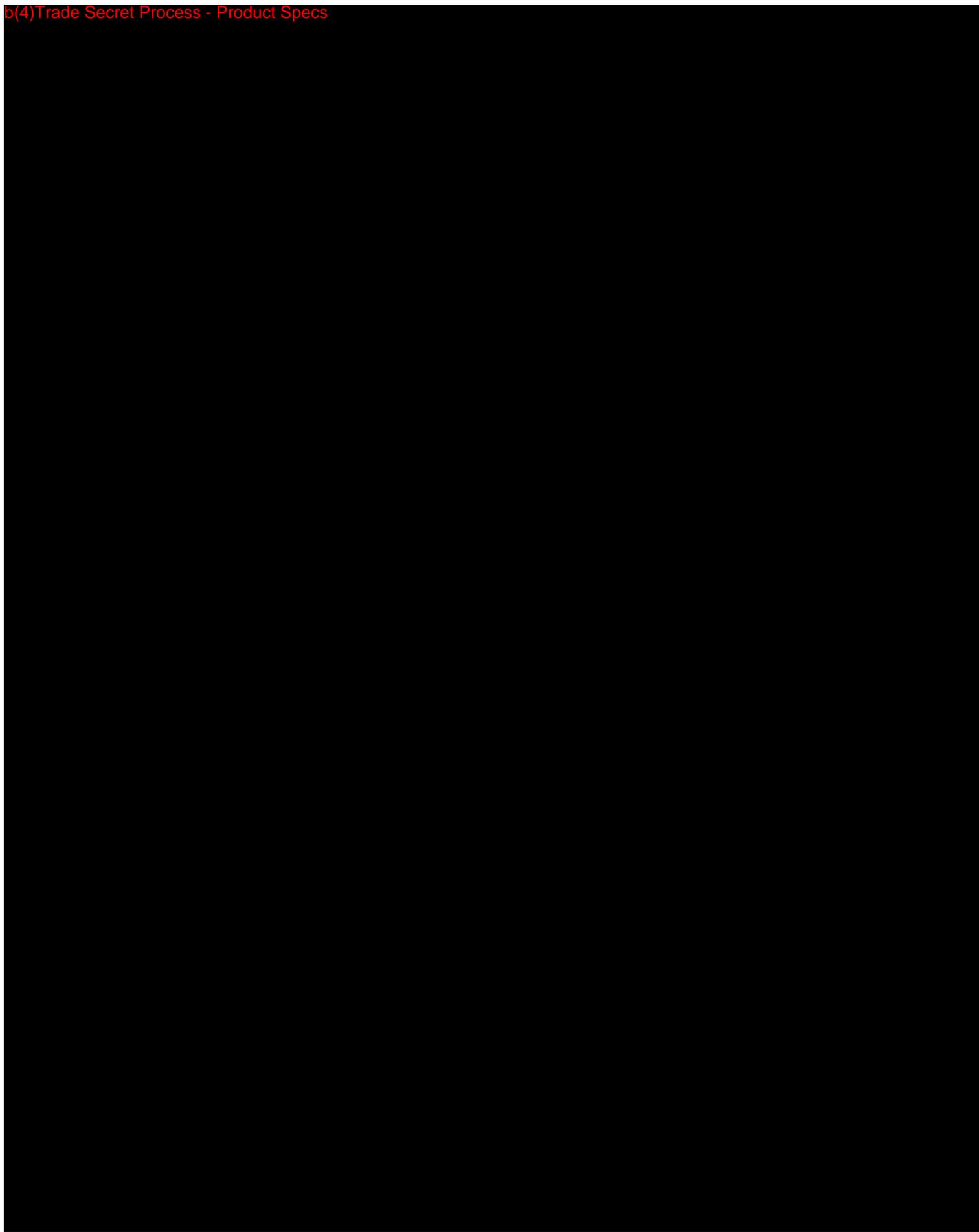


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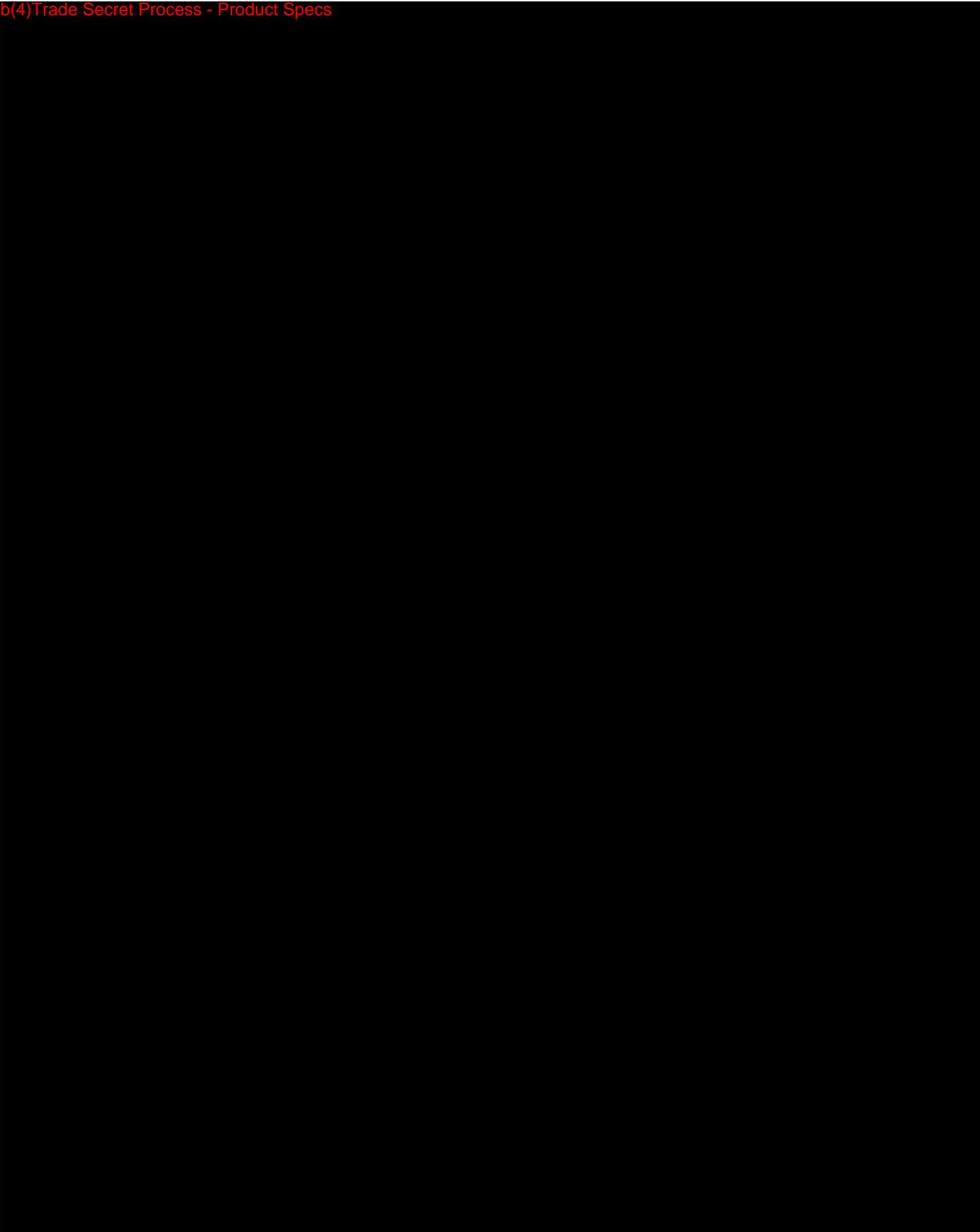
b(4) Trade Secret Process - Product Specs



b(4)Trade Secret Process - Product Specs



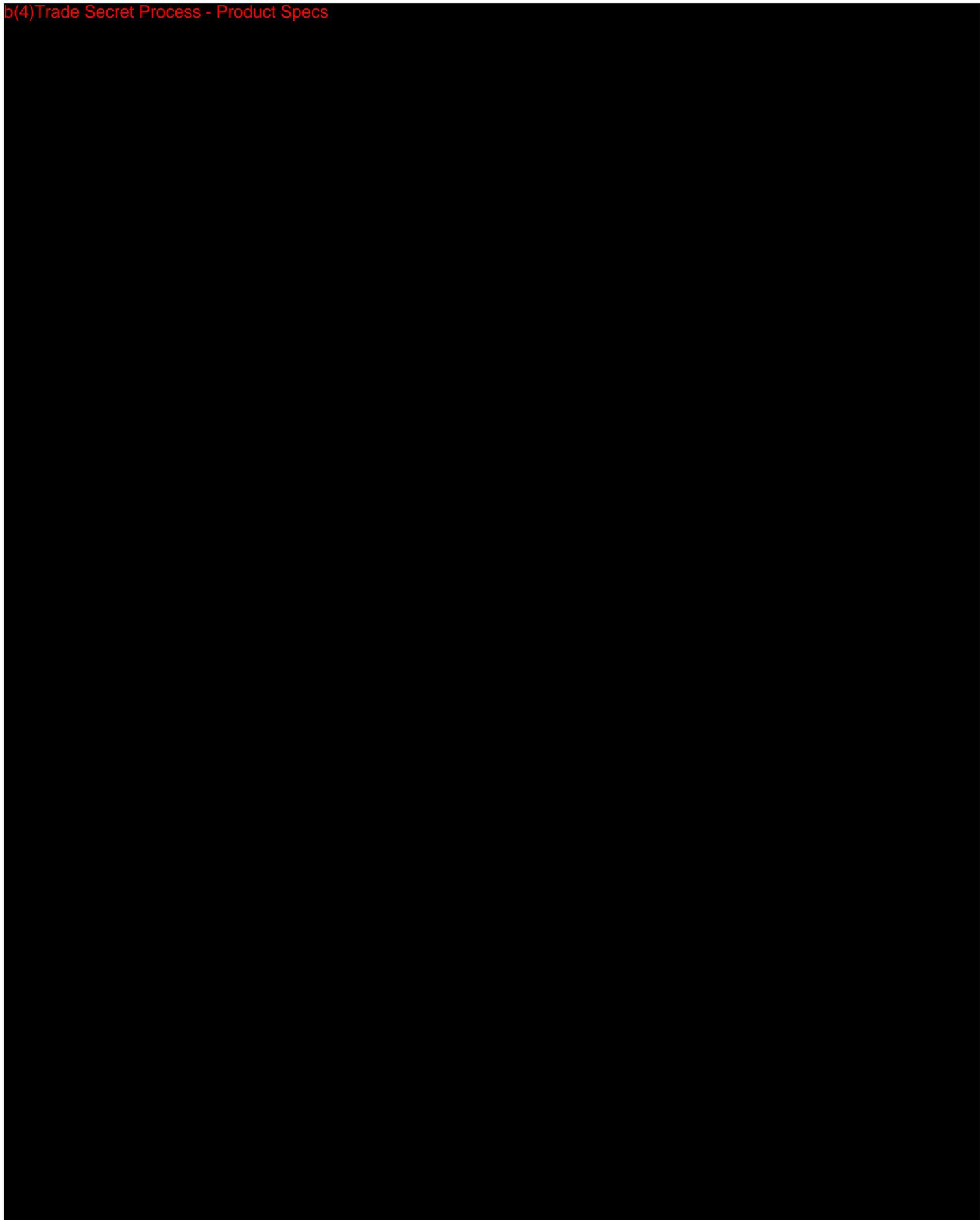
b(4)Trade Secret Process - Product Specs



b(4)Trade Secret Process - Product Specs



b(4)Trade Secret Process - Product Specs



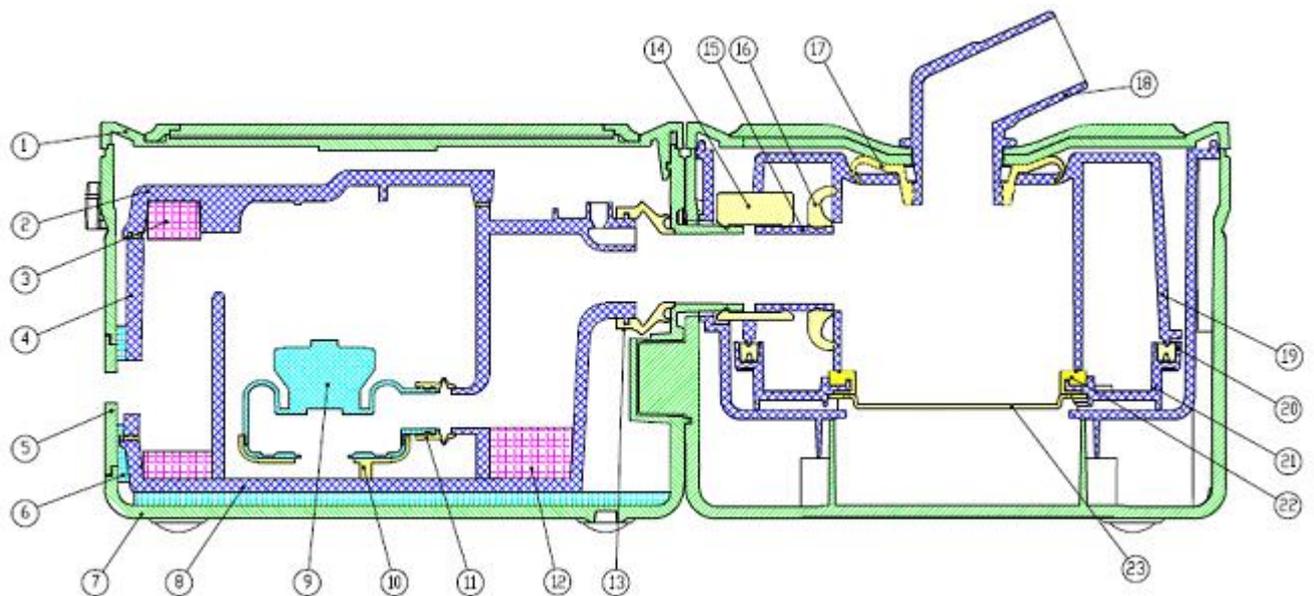
Section 9: Device Description

1. Intended use

The 3B and BMC RESmart GII CPAP and Auto-CPAP devices (also sold as the 3B Luna CPAP and Auto-CPAP devices) are intended to deliver positive pressure for the treatment of Obstructive Sleep Apnea. The optional integrated humidifier is indicated for the humidification and warming of air from the flow generator device. These devices are intended for use by prescription in the home or hospital/institutional environment on adult patients.

2. Construction of CPAP/Auto CPAP system

This device consists of an air blower, pressure/flow monitoring, pressure controlling, user interface and heated humidifier. The operation of the device is illustrated in the following block diagram:



1	Shield Top
2	Upper Noise Reduction Cover
3	Sponge
4	Middle Noise Reduction Cover
5	Filter Cap
6	Filter Foam
7	Shield Bottom
8	Lower Noise Reduction Cover
9	Blower
10	Support
11	Blower Sealing Element
12	Sponge

13	Connective Sealing Element
14	Humidifier Air Inlet Sealing Element
15	L-shaped Tube
16	L-shaped Tube Sealing Element
17	Humidifier Sealing Element
18	Air Outlet Tube
19	Water Chamber Top Cover
20	Water Chamber Sealing Element
21	Water Chamber Lower Cover
22	Water Chamber Sealing Element
23	Water Chamber Heater Plate

The air blower consists of a DC brushless motor, turbofan and shell etc. The fresh air is sucked in via inlet due to the vacuum caused by working air blower. Intake air passes through a filter, removing particulate matter. The filtered air is compressed to the certain pressure and blown out via outlet. The outlet pressure is decided by the motor speed which is controlled by pressure control system.

3. Device Operation

The 3B and BMC RESmart GII CPAP and Auto-CPAP devices (also sold as the Luna CPAP and Auto-CPAP devices) have a real-time pressure/flow monitoring function. The sensors monitor the outlet air pressure and flow which provides the necessary feedback to control the speed of the DC brushless motor regulating outlet air pressure in real time. The monitoring system will detect air leakage from the mask or tubing, send feedback on the leak rate, allowing the pressure control system to correct for the loss of pressure. When the system is in standby mode, the pressure monitoring system remains active and can detect respiration into a mask and automatically turn the device on. While in operation, the pressure/flow change caused by high leakage will also be detected, and the alarm and auto-off feature are triggered.

The device controls, settings, and system status are displayed by the user interface, which is composed of buttons and an LCD screen. The backlit LCD screen displays the system status and parameters. The buttons consist of knob, mute, and ramp user buttons. Users can control and set up the device with these buttons.

The heated humidifier is used to increase the outlet air temperature and humidity. It can be removed and assembled easily. It consists of a heated plate and water chamber. The water is heated and thus the temperature and humidity will be increased. The humidifier is controlled and powered by the main device. The temperature sensors ensure the

desired temperature and safety.

There are no mechanical differences between the CPAP and Auto CPAP devices. The units are mechanically identical, and the difference in operation is implemented entirely by software. The CPAP device is simply the Auto CPAP device with the auto pressure adjusting software module disabled. The output treatment pressure of CPAP is set by physician and fixed, whereas this pressure is adjusted automatically on Auto CPAP system by tracking patient's respiration and airflow.

4. Alerts

The CPAP/ Auto CPAP devices have mainly two types of alerts, a leakage alert and a power-off alert. The leakage alert may be enabled or disabled. If it is enabled, an audible alert will sound if the air leakage exceeds 150LPM, signifying mask or tube removal or damage to the mask or tube. In addition, there is an audible alert when the power supply is turned off. This function is always enabled and the audible signal can be silenced by the pressing of any button. Please refer to the document "Software document" for other types of alerts.

5. Automatic altitude adjustment

The CPAP and Auto CPAP devices can deliver the correct pressure when the device is located at different altitudes even if there is leakage in the patient circuit. However, when the leakage is too high, the device should make an audible alert.

The calculation of leakage is influenced by the altitude. If the altitude is high enough, the device will calculate a higher value of leakage than is actually occurring, which causes the device to emit a false alert. While the devices auto-adjust for altitude, the correct setup of altitude will prevent the device from giving out a false alert. The altitude can be set manually at 3 levels according to the following parameters: 0 = less than 2,460 ft (750m); 1 = 2,460 to 4,921 ft (750m to 1500m); 2 = > 4,924 ft (>1501m).

6. Modes

The CPAP only functions in one mode, the CPAP mode which provides air pressure at a constant level. By contrast, the Auto CPAP can work in both CPAP mode and Auto mode. In Auto mode, the device can provide air pressure at a customized, regularly adjusted level. The pressure is adjusted according to the patient's respiration.

7. Safety Mechanisms

Based on the risk analysis, the relevant risk control measurements were adopted in both hardware and software.

The software allows for a maximum pressure of 25 cmH2O.

A reset module independent of the pressure control module is designed to monitor the output pressure, if the pressure rises above 25 cmH2O for over 5 seconds, it will reset the device. The software must send an output signal of "0" and "1" alternately to enable the blower control module. The output signal "0" and "1" is implemented in different processes. If the software malfunctions, the signal of "0" and "1" will not be sent alternately so that the blower module will be disabled, which prevents the device from malfunctioning.

The protective circuit of the hardware is designed with a fuse relay to cut off the circuit when overheating.

Prescription pressure settings are designed to be accessed only by the clinician or homecare provider. A specific button combination is required to access the Clinician's Menu, which avoids unintentional pressure setting changes by the patient. For this reason, the setting and maintenance functions of the device are intentionally omitted from the patient user manual.

The data can be saved in flash memory which can keep data valid as the power supply is interrupted, and verification is added during the saving process in case that the saved data is wrong or incomplete.

8. Data storage

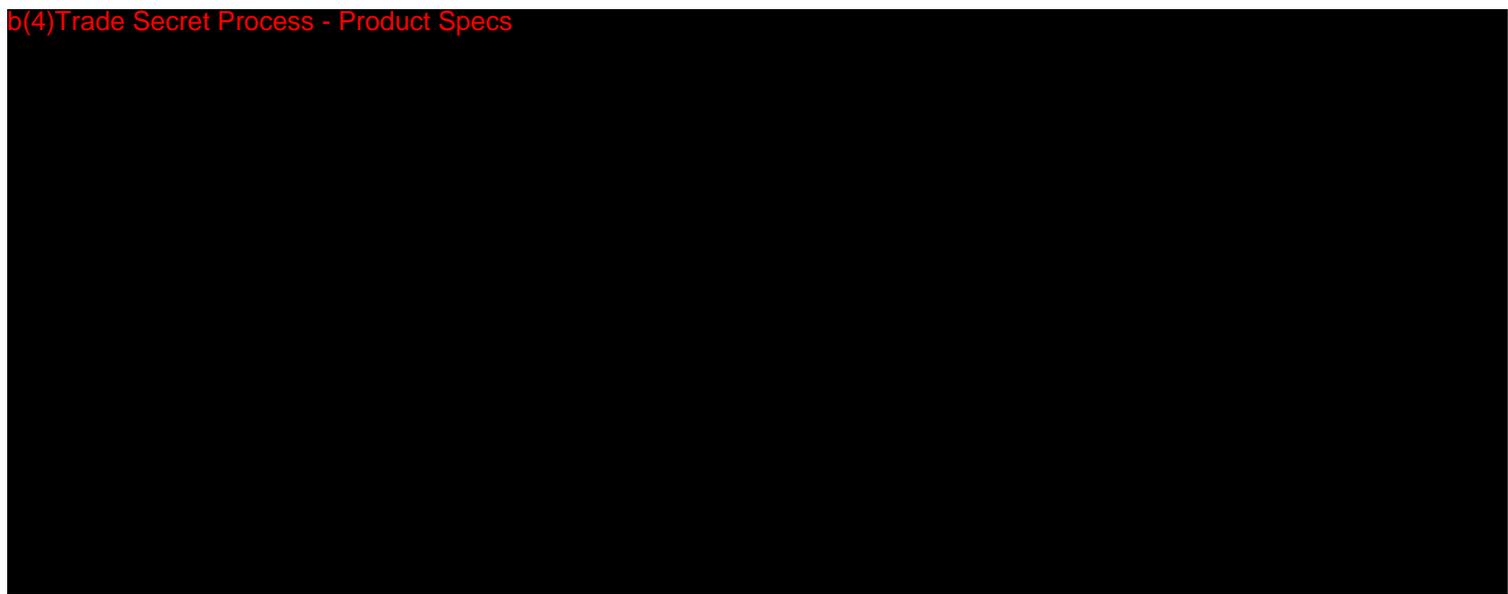
The SD card continuously records patient data and device operation data for patient compliance reporting and the monitoring of therapeutic effect and any problems in the therapeutic process. The recorded data includes, pressure, flow, blower rotation speed and snore and the maximum sample frequency is 20Hz. The record also includes a system journal and respiration event data. The SD card can continuously store the user data for at least one year.

9. iCode

iCode refers to a method for obtaining summary sleep data. In general, the summary statistic sleep data is encoded into a 16 digit numeric string. The iCode encoding scheme outputs a numeric string containing the patient's sleep compliance data (i.e. hours of use, % of monthly use, etc.) to allow easy reporting of patient compliance data. A unique code is calculated to reflect patient treatment compliance in the last 1, 7, 30, 90, 182 and 365 days. Each set of data includes valid treatment days and its percentage of use, mean treatment time, P95, mean pressure, AHI and air leakage proportion. In order to avoid falsifying reporting, the iCode is coded into 16 bit ASCII characters with a checksum or a QR code displayed on the device screen. A sleep compliance report can be generated using either the QR Code or iCode numeric string by smartphone apps, an online report generator, or an online patient management system. The website or the smartphone app will decode the QR Code or the numeric string and generate a compliance report as a pdf file.

10. Software Algorithms

b(4)Trade Secret Process - Product Specs



b(4)Trade Secret Process - Product Specs

11. Product specification

Product types:

The CPAP and Auto-CPAP devices are offered in the following model configurations:

Type	Remarks
E-20C-H-O	Main Device of CPAP.
E-20AJ-H-O	Main Device of AUTO CPAP; Display is 2.4inch.
E-20A-H-O	Main Device of AUTO CPAP; Display is 3.5inch.
H60	Humidifier.

Device Size

Dimensions: 170×196×118 mm

290×196×134 mm (with H60 heated humidifier)

Weight: <1.5kg

<2.5kg (with H60 heated humidifier)

Product Use, Transport and Storage

	Operation	Transport and Storage
Temperature:	5 to 35°C	-20 to 70°C
Humidity:	<93% Non-condensing	<93% Non-condensing
Atmospheric Pressure:	760 to 1060hPa	500 to 1060 hPa

Standard Compliance

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

IEC 60601-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance
 - Collateral standard: Electromagnetic compatibility - Requirements and tests

ISO 17510-1 Sleep apnoea breathing therapy Part 1: Sleep apnoea breathing therapy equipment

ISO 8185 Respiratory tract humidifiers for medical use — Particular requirements for respiratory humidification systems

Mode of Operation

Continuous

AC Power Consumption

100 – 240VAC, 50/60Hz, Max 2A

Type of Protection Against Electric Shock

Class II Equipment

Degree of Protection Against Electric Shock

Type BF Applied Part

Degree of Protection Against Ingress of Water

IP22 –Anti-drip Equipment

Pressure Range

4 to 20 cmH₂O (in 0.5 cmH₂O increments)

Pressure Stability

±0.5cmH₂O

Sound Pressure Level

<30 dB, when the device is working at the pressure of 10 cmH₂O.

Maximum Flow

Test of Maximum Flow rate (According to ISO 17510-1:2007 Annex CC)

	Test Pressure				
	Pmin	Pmin + 1/4(Pmax-Pmin)	Pmin + 1/2(Pmax-Pmin)	Pmin + 3/4(Pmax-Pmin)	Pmax

Measured pressure at the patient connection port (cmH2O)	4	8	12	16	20
Average flow at the patient connection port(L/min)	103.6	101.6	102.5	102.1	102.9

Pressure Display Accy.

±0.5 cmH2O

Heated Humidifier:**Size** **Dimensions:** 120 × 196 × 134mm**Weight:** < 1 kg**Water Capacity** > 350 ml at recommended water level**Product Use, Transport and Storage**

	Operation	Transport and Storage
Temperature:	5 to 35°C	-20 to 70°C
Humidity:	≤ 93% Non-condensing	≤ 93% Non-condensing
Atmospheric Pressure:	760 to 1060 hPa	500 to 1060 hPa

Power Requirements

24V DC 1.5A max

Type of Protection Against Electric Shock

Class II Equipment

Degree of Protection Against Electric Shock

Type BF Applied Part

Degree of Protection Against Ingress of Water

IP22 –Anti-drip Equipment

Heater Settings

1 to 5 levels, the temperature of heating panel is controlled within the target range (104 to 176° F / 40° to 80° C).

Maximum Operating Pressure

40 cmH₂O

Pressure Drop with Humidifier

<0.4 cmH₂O at 60 LPM flow

Maximum Delivered Gas Temperature

<40°C

Humidity Range

>10 mg /L

12. Photo of the Product



CPAP/Auto CPAP System without the Humidifier (Display is 2.4inch)



Auto CPAP System without the Humidifier (Display is 3.5inch)



Humidifier

13. Accessories

The humidifier is an integrated unit, that snaps into place on the CPAP/APAP, but is sold separately.

The CPAP and Auto CPAP are not sold with mask, tubing or bacterial filters. These accessories may be purchased separately, and the product line is designed to accommodate standard CPAP tubing (22mm) for easy interconnectability of masks and air tubing.

SUBSTANTIAL EQUIVALENCE

The proposed RESmart GII CPAP and Auto-CPAP Systems (also sold as the Luna CPAP and Auto-CPAP System), is a second generation redesign of the predicate device, the RESmart (K132967). The purpose of the redesign was to make the device more aesthetically appealing and easier to use. To this end, the redesign effort included the addition of a larger color LCD with a graphical user interface and a cosmetic redesign of the enclosure. The second generation proposed device (GII) remains substantially equivalent to the predicate (K132967) in that both the proposed and predicate devices share the same intended use, operating principle, technology and manufacturing process.

I. Indication for Use

The predicate and proposed devices' indications for use are identical and are as follows:

The 3B and BMC RESmart GII CPAP and Auto-CPAP Systems are intended to deliver positive pressure for the treatment of Obstructive Sleep Apnea. The optional integrated humidifier is indicated for the humidification and warming of air from the flow generator device. These devices are intended for single patient use by prescription in the home or hospital/institutional environment on adult patients.

Both systems are for prescription use only.

II. Operation of the Device

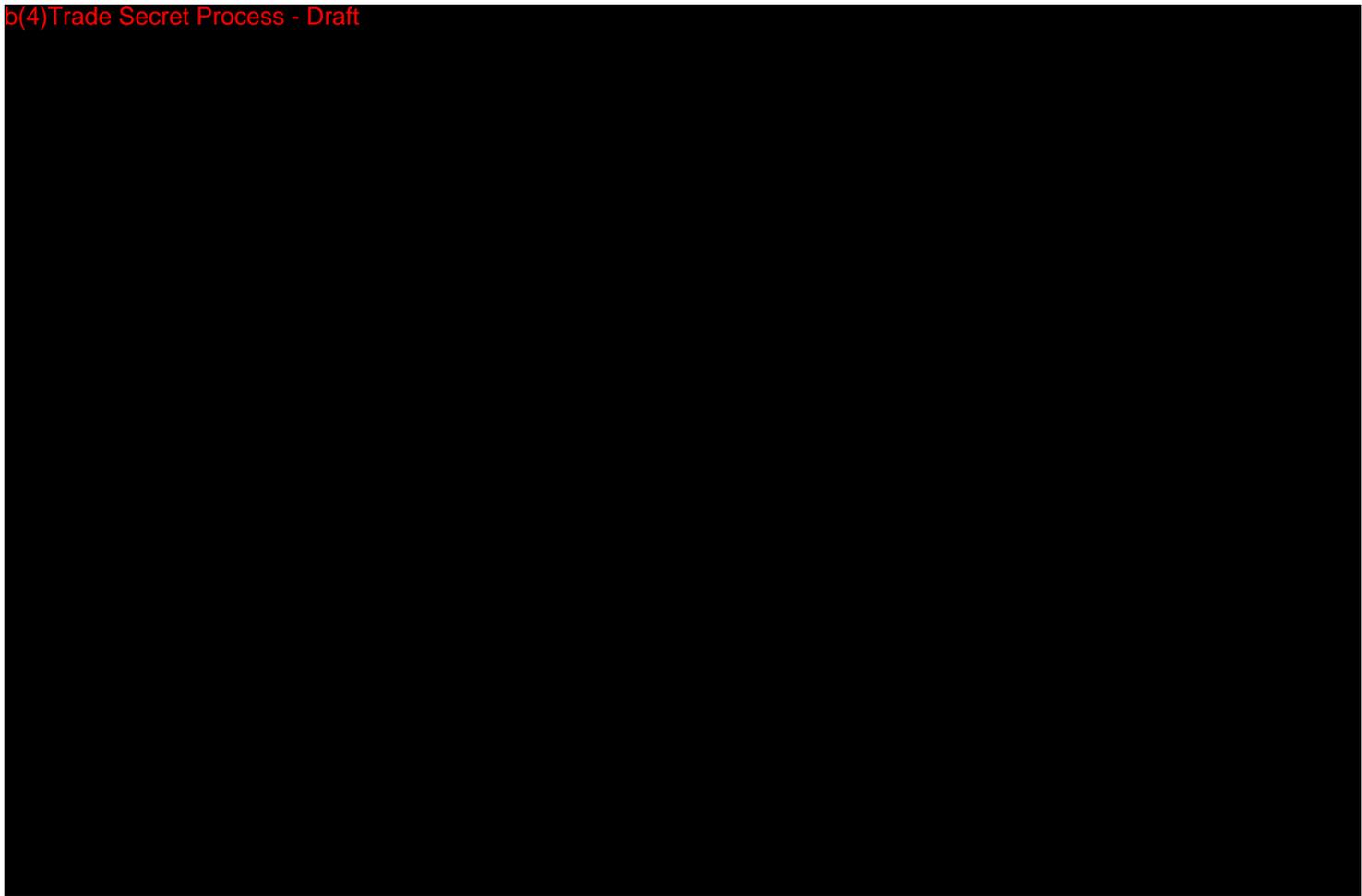
The RESmart GII System treats sleep apnea by delivering positive pressure to the patient's airway at a set pressure controlled by the device's motor speed. A pressure sensor and a flow sensor detect two key signals: pressure and flow rate. This creates a closed-loop feedback pressure control system that allows real time monitoring of respiration events. In response to these feedback signals, the device adjusts motor speed to deliver the prescribed pressure. In responding to pressure fluctuations occurring when

the patient breathes, the motor may operate at a constant speed, accelerate, or decelerate to respond on a breath-by-breath basis to variations in air pressure in the air circuit. The comprehensive performance of the motor, drive system and air circuit is measured through static pressure stability and dynamic pressure stability. The internal control mechanism, including blower fan, controller board, processor board and power supply of both the predicate and proposed device remain unchanged. Bench testing confirms that performance of both the predicate and proposed devices are substantially equivalent (See Appendix N, Comparative Performance Bench Testing of Predicate and Proposed Device).

There are no changes involving the software logic or algorithm of the proposed device, so the clinical efficacy of the both predicate and proposed devices remain unchanged.

III. Biocompatibility

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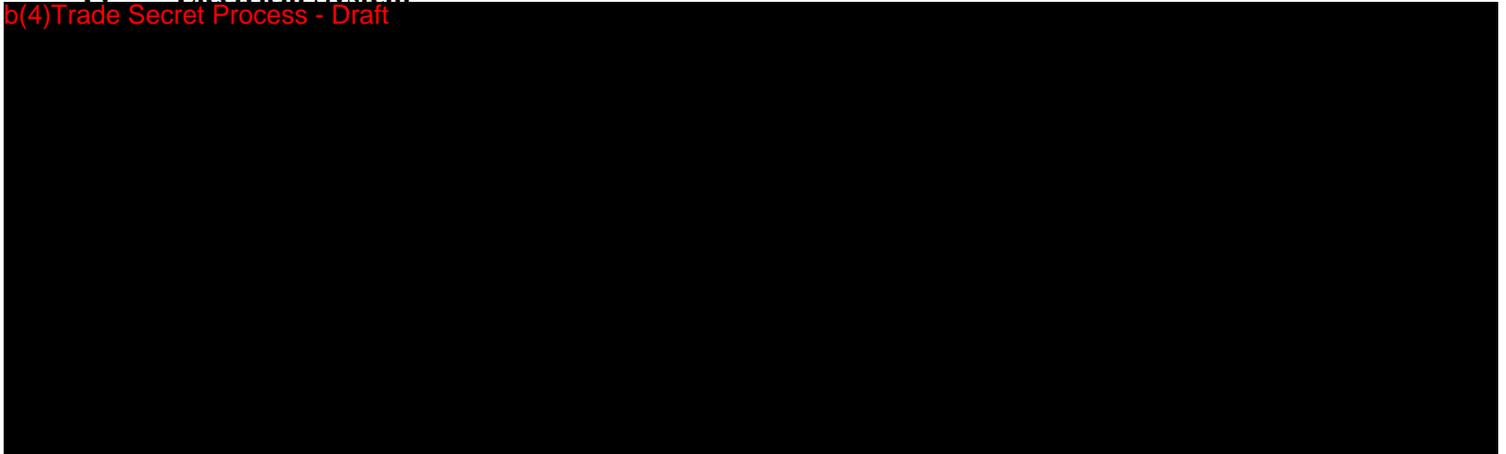


b(4)Trade Secret Process - Draft



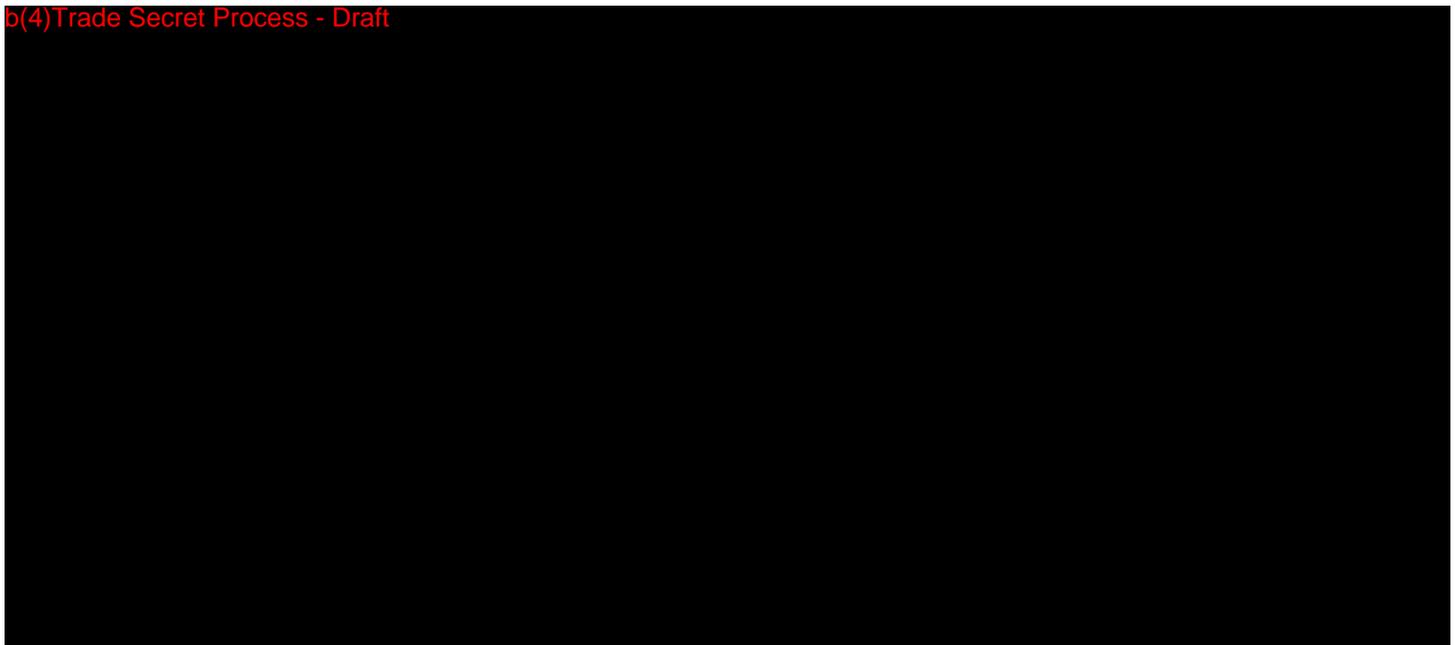
IV. Electrical System

b(4)Trade Secret Process - Draft



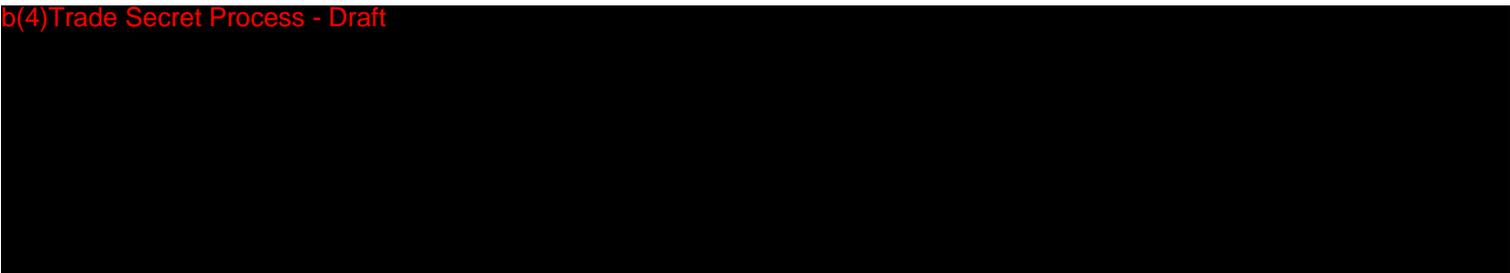
V. Air Quality Testing

b(4)Trade Secret Process - Draft



VI. Changes to Labeling

b(4)Trade Secret Process - Draft



CONCLUSION

Based on the foregoing, the proposed RESmart GII CPAP and Auto-CPAP System remains substantially equivalent to the predicate RESmart CPAP and Auto-CPAP System K132967 in that the systems share the same intended use, operating principle, technology, and manufacturing process.

b(4)Trade Secret Process - Draft



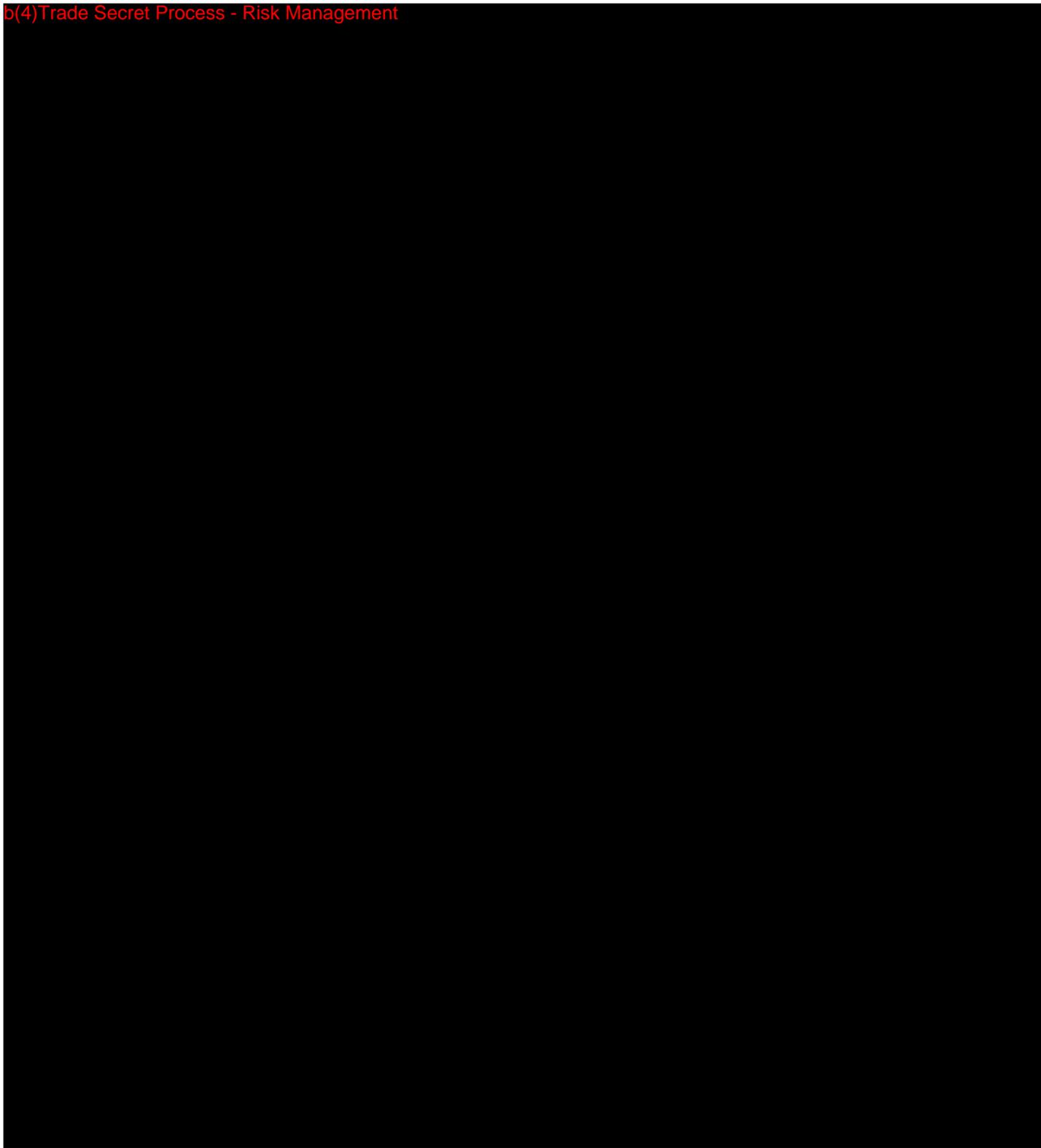
Summary of Risk Management and Risk Analysis

b(4) Trade Secret Process - Risk Management

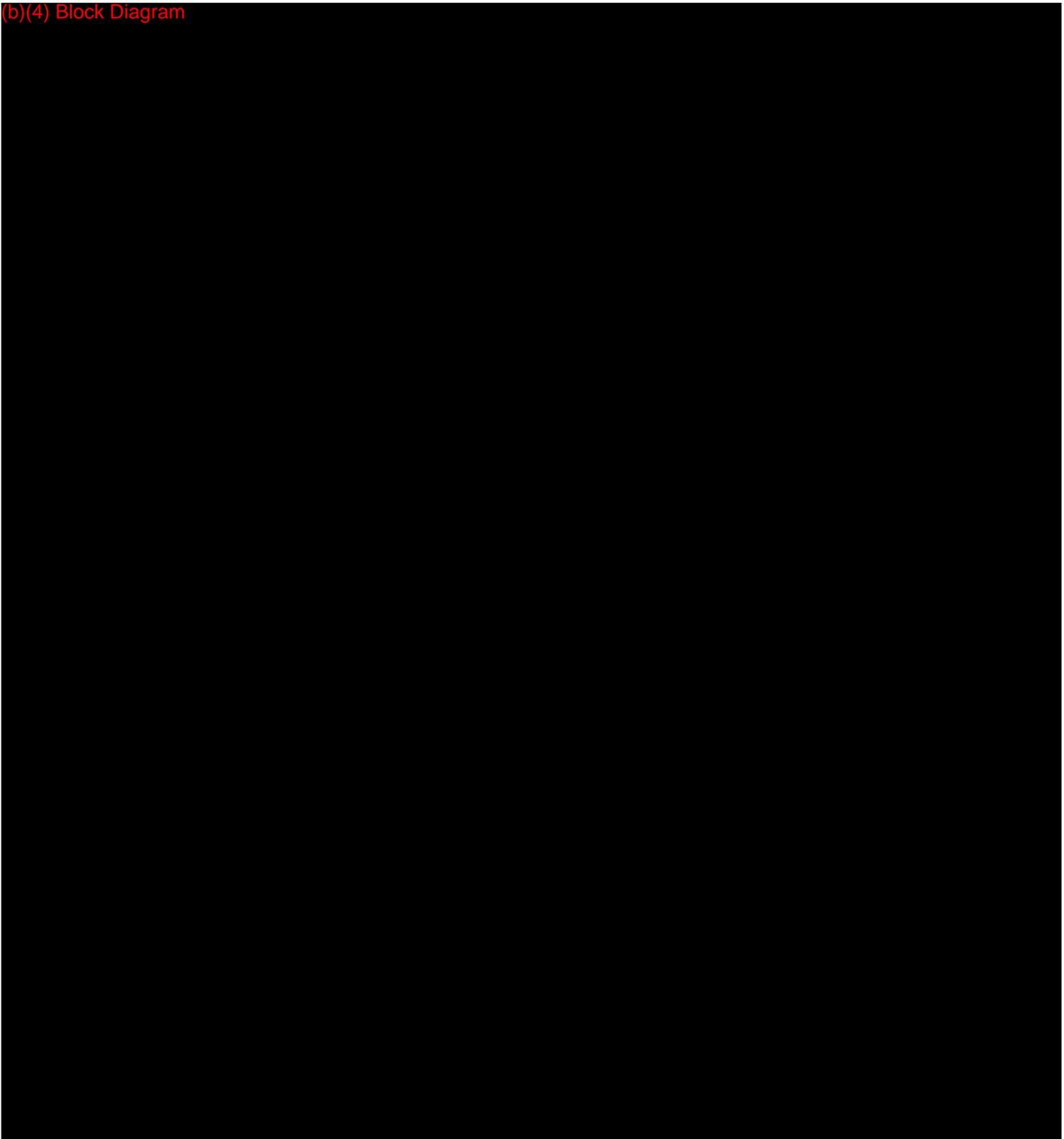


Section 13: BIOCOMPATIBILITY OF MATERIALS

b(4)Trade Secret Process - Risk Management



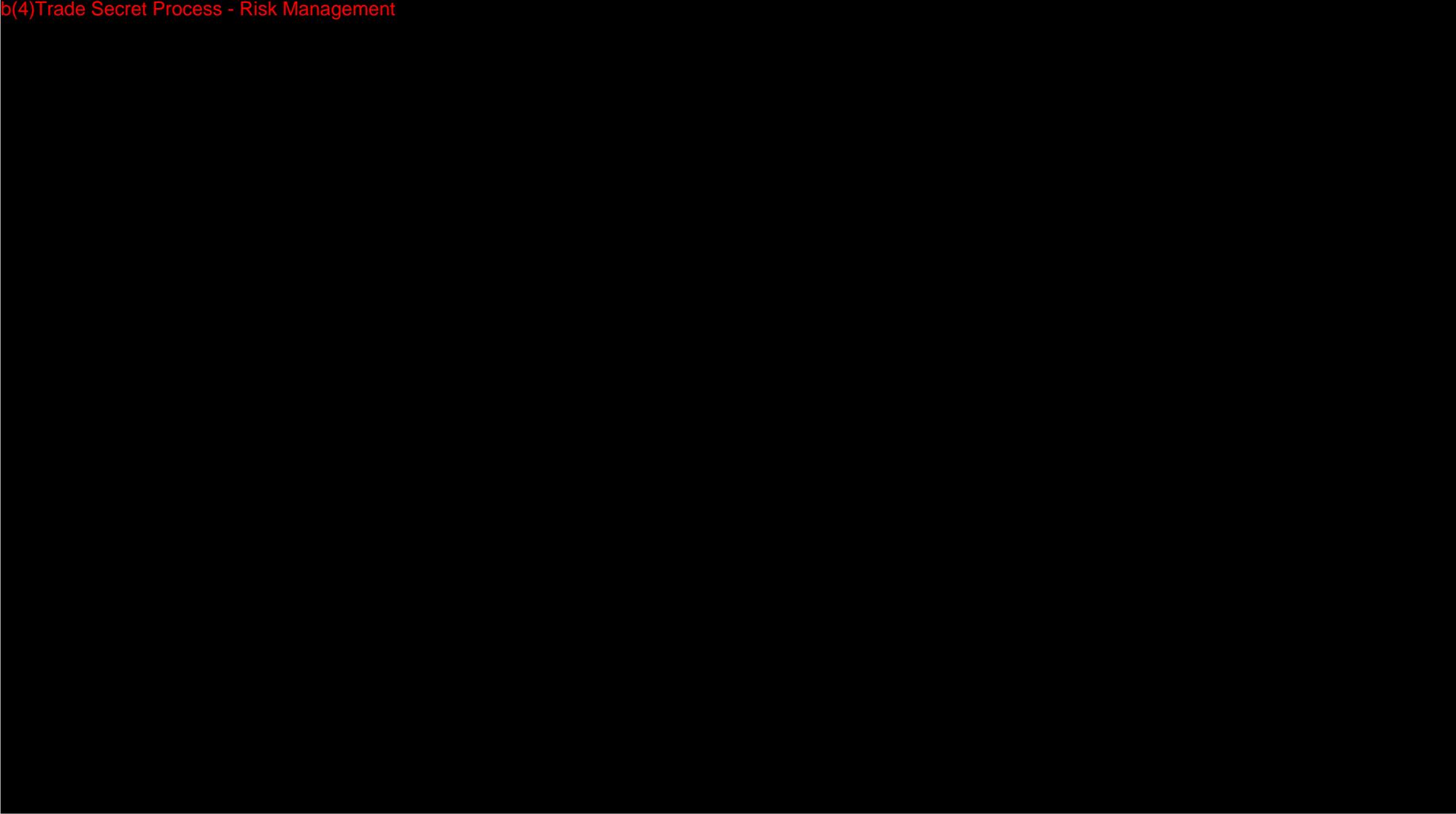
(b)(4) Block Diagram



b(4)Trade Secret Process - Risk Management



b(4)Trade Secret Process - Risk Management

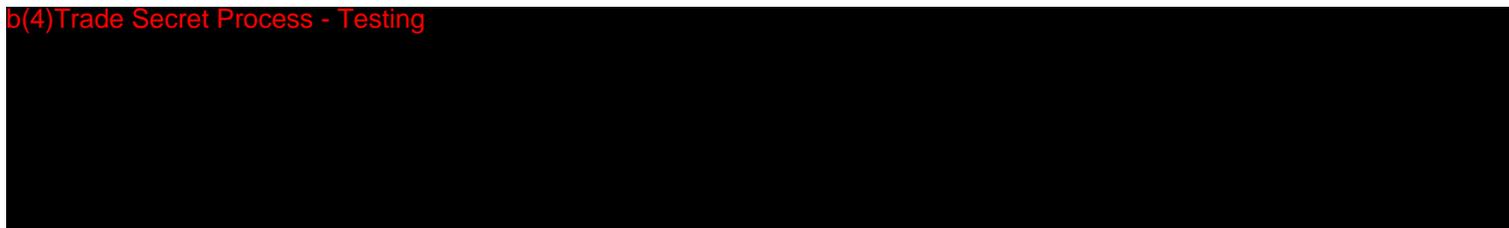


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b(4) Trade Secret Process - Testing



b(4)Trade Secret Process - Testing





E-20 System

E-20C-H-O E-20A-H-O E-20AJ-H-O



3BTM

*Solutions in Sleep Therapy*TM

User Manual

www.3Bproducts.com

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1. Symbols

1.1 Control Buttons

-  Ramp Button
-  Mute Button
-  Knob

1.2 Device Symbols

-  Follow Instructions for Use
-  Operating Instructions
-  Type BF Applied Part
-  Class II (Double Insulated)
-  AC Power
-  DC Power
- IP22 ≥ 12.5 mm Diameter, Dripping (15° tilted)
-  Hot Surface
-  Serial Number of the Product
-  Manufacturer
-  Authorized Representative in the European Community
-  European CE Declaration of Conformity
-  SD Card
-  Water Filling Prohibited Here
-  Water Inlet
-  Directional Indicator for Removing the Water Inlet Cap
-  Directional Indicator for Screwing the Water Inlet Cap

2. Warning, Caution and Important Tip

WARNING!

Indicate the possibility of injury to the user or operator.

CAUTION!

Indicate the possibility of damage to the device.

IMPORTANT TIP!

Place emphasis on an operating characteristic.

Warnings, Cautions, and Important Tips appear throughout this manual as they apply.

3. Intended Use

The 3B and BMC RESmart CPAP and Auto-CPAP Systems are intended to deliver positive pressure for the treatment of Obstructive Sleep Apnea. The optional integrated humidifier is indicated for the humidification and warming of air from the flow generator device. These devices are intended for single patient use by prescription in the home or hospital/institutional environment on adult patients.

WARNINGS!

- This device is intended for adult use only.
- This device is not intended for life support.
- The instructions in this manual are not intended to supersede established medical protocols.

CAUTION!

- This device is restricted to sale by or on the order of a physician.
- The device is intended for use by operators trained or experienced in similar equipment.
- The patient is an intended operator.
- Cleaning and disinfection can be performed by the patient.

IMPORTANT!

- Read and understand the entire user manual before operating this system. If you have any questions concerning the use of this system, contact your home care provider or health care professional.

4. Contraindications

Studies have shown that the following pre-existing conditions may contraindicate the use of positive airway pressure therapy for some patients:

Absolute Contraindications: pneumothorax, mediastinal emphysema; cerebrospinal fluid leak, traumatic brain injury, or pneumocephalus; shock caused by a variety of conditions before treatment; active epistaxis; upper gastrointestinal bleeding before treatment; coma or impaired consciousness making the use of mask during therapy impossible; giant vocal fold polyp, etc.

Relative Contraindications: severe coronary heart disease complicated with left ventricular failure, acute otitis media, excessive respiratory secretions and weak cough, weak spontaneous breathing, nasal or oral tracheal intubation and tracheotomy, severe nasal congestion caused by a variety of conditions, lung bullae, and allergies to breathing masks, etc.

The following side effects may occur during treatment:

- Dryness of the mouth, nose and throat
- Abdominal bloating
- Ear or sinus discomfort
- Eye irritation
- Skin irritation due to the use of a mask
- Chest discomfort

IMPORTANT!

- An irregular sleep schedule, alcohol consumption, obesity, sleeping pills, or sedatives may aggravate your symptoms.

CAUTION!

- Contact your health care professional if symptoms of sleep apnea recur. Contact your health care professional if you have any questions concerning your therapy.

5. Specifications

Device Size

Dimensions: 170 × 196 × 118 mm, or 290 × 196 × 134 mm (with the humidifier)

Weight: 1.5 kg, or 2.5 kg (with the humidifier)

Product Use, Transport and Storage

	Operation	Transport and Storage
Temperature:	5 to 35° C (41° F to 95° F)	-20 to 70° C (-4° F to 158° F)
Humidity:	15% to 93% Non-condensing	15% to 93% Non-condensing
Atmospheric Pressure:	760-1060 hPa	760-1060 hPa

Mode of Operation

Continuous

Work Mode

CPAP, AUTO

SD Card

With a capacity ≥ 2 G, the SD card can record patient data and fault information. Furthermore, the language pack stored on the SD card enables you to change the language of the device.

AC Power Consumption

100–240 V AC, 50/60 Hz, 2.0 A max

Type of Protection Against Electric Shock

Class II Equipment

Degree of Protection Against Electric Shock

Type BF Applied Part

Degree of Protection Against Ingress of Water

IP22

Pressure Range

4 to 20 cmH₂O (in 0.5 cmH₂O increments), ≤ 30 cmH₂O under single fault conditions.

Pressure Display Accuracy

±(0.5cmH₂O + 4%)

Pressure Stability

4 to 20 cmH₂O (±1 cmH₂O)

Ramp

The ramp time ranges from 0 to 60 minutes

Sound Pressure Level

< 30 dB, when the device is working at the pressure of 10 cmH₂O.

Sound Power Level

< 38 dB, when the device is working at the pressure of 10 cmH₂O.

Maximum Flow

Test Pressure (cmH ₂ O)	4	9	15	20
Average Flow at the Patient Connection Port (l/min)	80	92	91	96

Tube

Length: 6 ft. (1.83 m)

The Form and the Dimensions of the Patient Connection Port

The 22 mm conical air outlet complies with ISO 5356-1

6. Available Therapies

The device delivers the following therapies:

CPAP- Delivers Continuous Positive Airway Pressure; CPAP maintains a constant level of pressure throughout the breathing cycle. If your health care professional has prescribed ramp for you, you can press **the Ramp button**  to reduce the pressure and then gradually increase the pressure to the therapeutic pressure setting so that you can fall asleep more comfortably.

Auto- Delivers CPAP therapy and provides an air pressure no less than the prescribed pressure based on the patient's needs.

7. Glossary

Apnea

A condition marked by the cessation of spontaneous breathing.

Auto-CPAP

Adjust CPAP pressure automatically to improve patient comfort based on monitoring of apnea and snoring events.

Auto Off

When this feature is enabled, the device automatically discontinues therapy whenever the mask is removed.

Auto On

With this feature, the device automatically initiates therapy when you breathe into the mask. This feature is always enabled.

CPAP

Continuous Positive Airway Pressure

iCode

A feature that is intended to give access to compliance and therapy management information.

LPM

Liters Per Minute

OSA

Obstructive Sleep Apnea

Patient Menu

The display mode in which you can change patient-adjustable device settings, such as the starting pressure for the Ramp feature.

Ramp

A feature that may increase patient comfort when therapy is started. It can reduce pressure and then gradually increase the pressure to the prescription setting so the patient can fall asleep more comfortably.

RESlex

A therapy feature that is enabled by your home care provider to provide pressure relief during exhalation.

Standby State

The state of the device when power is applied but the airflow is turned off.

8. Model

Model	Product Description			
	Product Contents	Work Mode	Size (mm)	Weight
E-20C-H-O	Main device (2.4-inch LCD), Tube, Humidifier (H60)	CPAP, AUTO	290(W)×196(D)×134(H)	2.5kg
E-20A-H-O	Main device (3.5-inch LCD), Tube		170(W)×196(D)×118(H)	1.5kg
E-20AJ-H-O	Main device (2.4-inch LCD), Tube		170(W)×196(D)×118(H)	1.5kg

9. Package Contents

After unpacking the system, make sure you have everything shown here:

No.	Articles	Num.	Notes
1	Main Device	1	
2	Humidifier	1	Optional
3	Shield	1	
4	Air Filter	2	
5	Power Adapter	1	
6	Power Cord	1	
7	Mask	1	
8	Tube	1	
9	SD Card	1	Optional
10	Carrying Case	1	
11	User Manual	1	
12	Quick Operation Manuel	1	
13	Warranty Card	1	

All parts and accessories do not contain latex. The expected service life of the main device is 5 years.

IMPORTANT!

- If any of the above parts are missing, contact your home care provider.
- Contact your home care provider for additional information on the available accessories of this device. When using optional accessories, always follow the instructions enclosed with the accessories.

WARNINGS!

- This device should only be used with the mask and accessories manufactured or recommended by 3B or with those recommended by your prescribing physician. The use of

inappropriate masks and accessories may affect the performance of the device and impair the effectiveness of therapy.

- The use of accessories other than those specified, with the exception of cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.
- All parts and accessories do not contain latex.

10. System Features

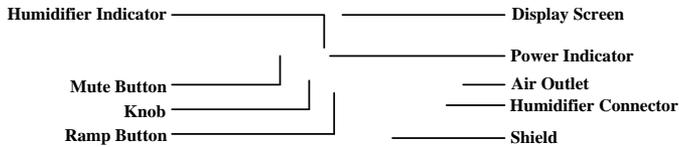


Fig. 10-1

Name	Function
Humidifier Indicator	Indicate the humidity level. There are five levels in total. The number of indicator lights that light up is directly proportional to the humidity level. If none of the indicator lights light up, it means the humidifier is turned off.
Mute Button	Press this button to mute the alert. However, if the problem causing the alert is not solved, the alert will sound again two minutes later.
Knob	Start treatment and adjust device settings
Ramp Button	Enable the Ramp feature
Display Screen	Display menus for operation, messages, monitoring data, etc.
Power Indicator	Indicate the power supply status
Air Outlet	Deliver pressurized air; connected to the tube or the air inlet of the humidifier
Humidifier Connector	Provide power to the humidifier which is connected to the main device
Shield	Connect the humidifier to the main device after this shield is removed.

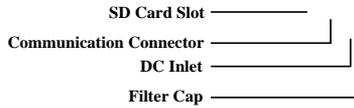


Fig. 10-2

Name	Function
SD Card Slot	Insert the SD card into this slot
Communication Connector	Connected to external equipment
DC Inlet	An inlet for the DC power supply
Air Filter and Filter Cap	Place the cap on the air filter, which is used to filter dust and pollen in the air entering the device.

11. First Time Setup

11.1 Placing the Device

Place the device on a firm, flat surface.

WARNINGS!

- If the device has been dropped or mishandled, if the enclosure is broken, or if water has entered the enclosure, disconnect the power cord and discontinue use. Contact your home care provider immediately.
- If the room temperature is warmer than 95°F (35° C), the airflow produced by the device may exceed 109.4°F (43° C). The room temperature must be kept below 95°F (35° C) while the patient uses the device.

CAUTIONS!

- If the device has been exposed to either very hot or very cold temperatures, allow it to adjust to room temperature (approximately 2 hours) before beginning setup.
- Make sure the device is away from any heating or cooling equipment (e.g., forced air vents, radiators, air conditioners).
- The device is not suitable for use in high humidity environments. Make sure that no water enters the device.
- Make sure that bedding, curtains, or other items are not blocking the filter or vents of the device.
- To avoid explosion, this device must not be used in the presence of flammable gases (e.g. anesthetics).
- Tobacco smoke may cause tar build-up within the device, leading to the malfunctioning of the

device.

- Air must flow freely around the device for it to work properly.

11.2 Installing the Air Filter and Filter Cap

- (1) Attach the air filter to the filter cap, as shown in Fig.11-1.

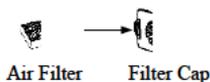


Fig. 11-1

- (2) Install the filter cap containing the air filter to the main device, as shown in Fig.11-2.

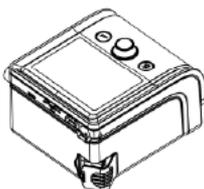


Fig. 11-2

CAUTION!

- The air filter must be in place when the device is operating.
- Installing the air filter and filter cap, device must be unplugged.

11.3 Connecting to Power

- (1) Insert the plug of the power adapter into the DC Inlet on the back of the device;
- (2) Connect the power cord to the power adapter;
- (3) Plug the other end of the power cord into the power outlet.

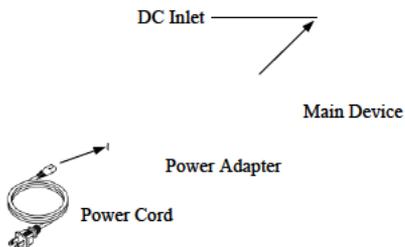


Fig. 11-3

WARNINGS!

- The device is powered on for use when the power cord and power adapter is connected. The **Knob** turns the blower On/Off.
- Use of the device at an AC voltage beyond the stated range (see Section 5 "AC Power Consumption") may damage the device or cause device failure

CAUTION!

- Inspect the power cord often for any signs of damage. Replace a damaged cord immediately.

IMPORTANT!

- After interruption and restoration of the power supply, the device will restore its pre-interruption working status automatically.
- To remove AC power, disconnect the power cord from the power outlet.

11.4 Assembling the Tube and Mask

(1) Connect one end of the tube to the air outlet of the main device, as shown in Fig.11-4. If the main device is used with a humidifier, connect one end of the tube to the air outlet of the humidifier, as shown in Fig.11-5.

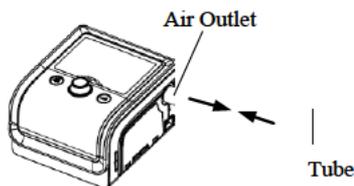


Fig. 11-4

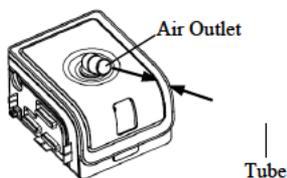


Fig. 11-5

(2) Connect the other end of the tube to the mask according to the user manual for the mask. Wear the mask.

WARNINGS!

- If multiple persons are going to use the device (e.g., rental devices), a low-resistance, main flow bacteria filter should be installed in-line between the device and tube. Pressures must be verified by your home care provider when alternate or optional accessories are in place.

- If you are using a mask with a built-in exhalation port, connect the mask's connector to the tube.
- If you are using a mask with a separate exhalation port, connect the tube to the exhalation port. Position the exhalation port so that the vented air is blowing away from your face. Connect the mask's connector to the exhalation port.
- If you are using a full-face mask (a mask covering both your mouth and nose), the mask must be equipped with a safety (entrainment) valve.
- In order to minimize the risk of CO₂ rebreathing, the patient should observe the following instructions:
 - Use the accompanying tube and mask provided by 3B.
 - Do not wear the mask for more than a few minutes while the device is not operating.
 - Use only masks with vent holes. Do not block or try to seal the vent holes in the exhalation port.

11.5 Using Oxygen with the Device

Oxygen may be added at the mask connection. Please observe the instructions listed below when using oxygen with the device.

WARNINGS!

- Connect the oxygen tube to the oxygen inlet of the mask.
- The oxygen supply must comply with the local regulations for medical oxygen.
- Turn on the device before turning on the oxygen. Turn off the oxygen before turning off the device. Explanation of Warning: When the device is turned off, but the oxygen flow still exists, oxygen may accumulate within the device's enclosure and pose a fire hazard. Turning off the oxygen before turning off the device will prevent oxygen accumulation in the device and reduce the risk of fire. This warning applies to most CPAP devices.
- Oxygen supports combustion. Keep the device and the oxygen container away from heat, open flames, any oily substances, or other sources of ignition. DO NOT smoke in the area near E-20A or the oxygen container.
- Sources of oxygen should be located more than 1 m from the device.

11.6 Inserting the SD Card

Insert the SD card into the SD Card Slot, as shown in Fig.11-6.

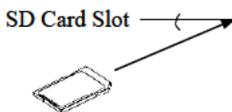


Fig. 11-6

If the SD card is inserted correctly, a symbol indicating correct insertion will appear in the Main Interface on the screen of the device, as shown in Fig.11-7.

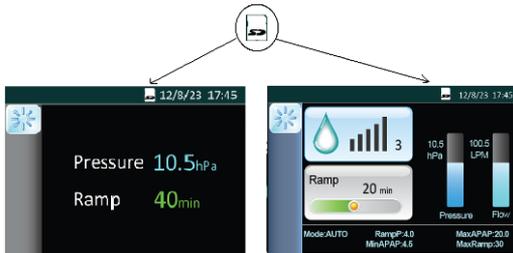


Fig. 11-7

If the SD card is inserted incorrectly or not inserted, a symbol indicating incorrect insertion or no SD card present will appear in the Main Interface on the screen of the device, as shown in Fig.11-8.

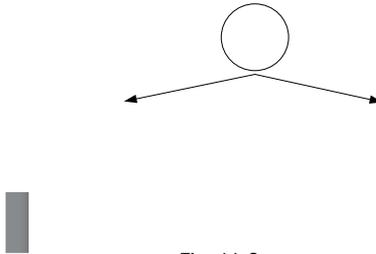


Fig. 11-8

CAUTION!

- To avoid data loss or any damage to the SD card, the SD card can only be removed after the main device stops delivering air.

11.7 Using the H60 Heated Humidifier

The H60 Heated Humidifier is available from your home care provider. The humidifier may reduce nasal dryness and irritation by adding moisture (and heat if applicable) to the airflow. For detailed information about the heated humidifier, please see the user manual for the heated humidifier.

11.8 Starting Treatment

Connect the device to a power outlet, press **the Knob** , and the device will start delivering air.

WARNINGS!

- Be sure to follow your physician's instructions on adjusting the settings! To order any accessories not included with this device, contact your equipment supplier.
- DO NOT connect any ancillary equipment to this device unless recommended by 3B or your

physician. If you suffer from chest discomfort, shortness of breath, stomach bloating, or severe headache when using the device, contact your physician or qualified medical personnel immediately.

12. Routine Use

12.1 Connecting the Tube

Connect the power cord, power adapter, and tube properly according to the instructions in the First Time Setup (Chapter 11). Connect the mask and headgear according to the user manual for the mask.

CAUTION!

- Before each use, examine the tube for any damage or debris. If necessary, clean the tube to remove the debris. Replace any damaged tube. Make sure that the mask does not leak.

12.2 Adjusting the Tube

Lie down on your bed, and adjust the tube so it is free to move if you turn during sleep. Adjust the mask and headgear until you have a comfortable fit and until there are no airflow leaks into your eyes.

12.3 Turning on the Airflow

Press **the Knob**  to turn on the airflow. The screen will display treatment pressure and other information.

12.4 Heating the Water in the Humidifier

Pay attention to the humidifier indicator lights when using the device with a humidifier. The indicator lights indicate the On/Off state of the humidifier. It is off when all indicator lights go out.

CAUTION!

- Observe the water level of the water chamber before using the humidifier. Make sure there is sufficient water in the water chamber, and avoid heating the humidifier with an empty water chamber.

12.5 Using the Ramp Button

Every time **the Ramp button**  is pressed, the pressure will drop to the initial pressure, and then gradually rise to the prescribed treatment pressure according to the preset ramp time, so as to make the patient fall asleep easily. The screen displays a real-time countdown of the remaining ramp time in minutes.

CAUTIONS!

- You can press **the Ramp button**  as often as you wish during sleep.
- The ramp feature is not prescribed for all users.

12.6 Turning the Device Off

Take off the mask and headgear, press **the Knob** , and the device will stop delivering air. Disconnect the power cord from the power outlet to power off the device.

CAUTION!

- If the airflow from the device is cold, place the tube under your quilt to reduce heat loss while you sleep.

13. Navigating the Patient Menu**13.1 Steps to Navigating the Patient Menu****13.1.1 Accessing the Main Interface**

Connect the power cord and power adapter properly. The screen displays the Main Interface shown in Fig.13-1 (only applies to E-20C-H-O, and E-20A-H-O), or the Main Interface shown in Fig.13-2 (only applies to E-20AJ-H-O).



Fig. 13-1



Fig. 13-2

13.1.2 Bringing up the Initial Setup Interface

From the Main Interface shown in Fig.13-1 or Fig.13-2, or when the device delivers air, press and hold **the Ramp button**  for three seconds. The screen displays the Initial Setup Interface of the Patient Menu, as shown in Fig.13-3.



Fig. 13-3

The first icon  on the left side of the screen indicates the Main Interface, and the second icon  indicates the Initial Setup Interface. As you turn **the Knob** , the cursor switches between the two icons, and the interface displayed on the screen changes accordingly.

13.1.3 Accessing the Setup Interface

When the cursor is on the icon , the screen displays the Setup Interface. Access the Setup Interface by pressing **the Knob** . The first option on the Setup Interface is then displayed in blue, as shown in Fig.13-4.

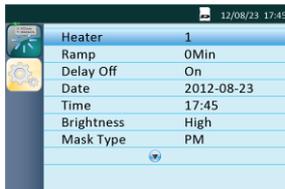


Fig. 13-4

13.1.4 Selecting Options

As you turn **the Knob**  clockwise, the cursor moves downwards from one option to another. As you turn it counterclockwise, the cursor moves upwards. When the cursor is on a certain option, press **the Knob** , and the option is then displayed in yellow, meaning that the option can now be adjusted, as shown by the **Heater** option in Fig.13-5.



Fig. 13-5

13.1.5 Adjusting Options

Adjust the option by turning **the Knob** . As shown in Fig.13-6, the **Heater** option is selected. As you turn **the Knob**  clockwise, the numbering increases, indicating a higher humidity level. As you turn **the Knob**  counterclockwise, the numbering decreases, indicating a lower humidity level. At this moment, the **Heater** option is still displayed in yellow, as shown in Fig.13-6.



Fig. 13-6

13.1.6 Confirming Adjustments

Confirm your adjustment to an option by pressing **the Knob** . The option is then displayed in blue, as shown in Fig.13-7.

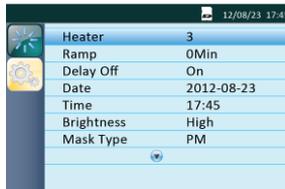


Fig. 13-7

13.1.7 Turning Pages

When the cursor is on **Mask Type**, the last option shown in Fig.13-7, the remaining options will appear on a new page if you continue to turn **the Knob**  clockwise, as shown in Fig.13-8.



Fig. 13-8

Note:   are page turning symbols.

13.1.8 Exiting the Patient Menu

(1) Returning to the Initial Setup Interface

Move the cursor to the **Back** option by turning **the Knob** , as shown in Fig.13-9.



Fig. 13-9

Press **the Knob** , the cursor jumps to the second icon  on the left side of the screen. The screen displays the Initial Setup Interface, as shown in Fig.13-10.

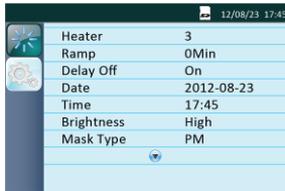


Fig. 13-10

(2) Returning to the Main Interface

Move the cursor to the **Home** option by turning **the Knob** , as shown in Fig.13-11.



Fig. 13-11

Press **the Knob**  to exit the Patient Menu. The screen will display the Main Interface shown in Fig.13-1 or Fig.13-2.

13.2 Options of the Patient Menu and Corresponding Descriptions

Option	Range	Description
Heater	Off, 1-5	There are five humidity levels available. As the numbering increases, the humidity rises accordingly. "Off" means the humidifier is turned off. The default setting is "2."
RESlex	Off, 1-3	This feature enables the device to automatically reduce the treatment pressure when the patient exhales, so as to make the user more comfortable. The higher the numbering is, the more pressure the device reduces. "Off" means this feature is disabled. The default setting is "Off."
Ramp	0-Ramp Max	In order to increase comfort and help the patient fall asleep easily, the pressure can increase gradually, when the Ramp feature is enabled. The ramp time during which the initial pressure rises to the prescribed treatment pressure can be adjusted. As you turn the Knob  to the nearest point, the numbering increases or decreases by five minutes. The default setting is "10 minutes." The screen displays a real-time countdown of the remaining ramp time in minutes.

Delay	On/Off	When the humidifier is on, this feature allows the airflow to continue for about 15 minutes at a low pressure (about 2 cmH ₂ O) after you press the Knob  to discontinue treatment. This will blow off the vapor left in the humidifier to avoid any damage to the device. When this feature is set to "Off," which means it is disabled, the airflow stops delivering air instantly after you press the Knob  . The default setting is " On. "
Date	2000-01-01 — 2099-12-31	Setting date by adjusting this option.
Time	—	Setting time by adjusting this option.
Brightness	High/Low	Setting screen brightness by adjusting this option. The default setting is " High. "
Mask Type	FM; NM; PM; A, B, C	There are three mask types available, namely FM (full-face mask), NM (nasal mask), and PM (nasal pillow mask). The default mask type is "NM," but the patient can choose other suitable masks as well. When selecting masks other than the above three types of 3 masks, the patient can identify the masks as A, B, or C.
Use Time	0-50000Hrs	Use Time displays how long has the equipment been used by the user. The data can be erased
iCode	iCode I, iCode II	iCode provides access to the patient's compliance data during a recent time period. The iCode I mode displays data in sequences of characters, and the iCode II mode displays data in two-dimensional codes.

14. Alert

Alert Message	Description
Loss of Power!!!	An audible alert will sound if the device is accidentally disconnected from power when it is delivering air. Note: (1) The alert will not sound if power failure occurs when the device is in standby state. (2) No alert message on the screen during a power failure.
Ventilator Inoperative!!!	An audible alert will sound if no airflow comes out of the machine; the screen will display " Ventilator Inoperative!!! "
Leak!!	When the airflow is on, an audible alert will sound if the air leak rate exceeds 150 l/minLPM; the screen will display " Leak!! "
Low Input Voltage!!	If you use a battery rather than an external power adapter to power the device, an audible alert will sound when the battery is low; the screen will display " Low Input Voltage!! "

Humidifier Failure!!	when humidifier is applied , an audible alert will sound when the humidifier fails to work; the screen will display "Humidifier Failure!!"
Please Replace Filter!	When the Filter Alert feature is enabled, an audible alert will sound if an air filter has been used for more than six months; the screen will display "Please Replace Filter!"
SD Card Full!	The screen will display "SD Card Full!" if the SD card has reached its maximum capacity.
Remove and Reinsert!	The screen will display "Remove and Reinsert!" if the SD card fails to work.

15. Cleaning and Disinfection

WARNINGS!

- Regular cleaning of the device and its accessories is very important for the prevention of respiratory infections.
- To avoid electric shock, always unplug the device before cleaning.
- Use washing liquid that is nontoxic to humans and does not cause allergies in humans.
- Follow the manufacturer's instructions on cleaning the mask and tube and on determining the frequency of cleaning.
- Before cleaning, check whether the device has been disconnected from the power supply, whether the power cord has been unplugged, and whether the water chamber of the humidifier has cooled down. Make sure the heater plate has cooled down to room temperature, so you do not get burned.

CAUTIONS!

- Overheating of the materials could lead to early fatigue of these materials.
- Do not use solutions containing chlorinated lime, chlorine, or aromatic to clean the device and its accessories. Liquid soap containing the humidifying agent or antimicrobials should not be used either. These solutions may harden cleaned materials or reduce their life.
- Do not clean or dry the device and its accessories when the temperature is higher than 80° C (176°F). High temperatures could reduce product life.
- Do not immerse the device in any fluids.

15.1 Cleaning the Mask and Headgear

For details, refer to the cleaning instructions in the user manual for the mask.

15.2 Cleaning the Water Chamber of the Humidifier

For details, refer to the cleaning instructions in the user manual for the humidifier.

15.3 Cleaning the Enclosure

Wipe the surface of the device with a soft, slightly damp cloth.

CAUTION!

- The device can only be used after the enclosure is dry, so that no moisture enters the device.

15.4 Cleaning the Tube

- (1) Remove the tube from the device and mask before cleaning.
- (2) Clean the tube in warm water which contains washing liquid, and then rinse it in clean water thoroughly.
- (3) After cleaning, air-dry the tube in a cool, well-ventilated area, and avoid direct sunlight. It takes approximately 30 minutes to completely air-dry the tube. Check whether the tube is completely dry before re-use.

15.5 Replacing the Air Filter

- (1) Open the air filter cap to remove the air filter.
- (2) Put the new air filter in the filter area, and then place the filter cap back properly.

CAUTIONS!

- To avoid material damage, do not place the spare air filter in direct sunlight, humid environments, or temperatures below the freezing point. The air filter should be replaced every 6 months (It may be replaced more frequently based on actual sanitary conditions).
- Operating the device with a dirty air filter may stop it from working properly and may cause damage to the device.

15.6 Disinfection

Generally speaking, if you have strictly followed the above cleaning instructions, you do not have to disinfect the device and/or humidifier. If the device is contaminated or used in clinical trials, you may purchase disinfectants from a pharmacist to disinfect the device.

See the Disinfection section of the humidifier user manual for more information on the disinfection of the water chamber.

CAUTIONS!

- Disinfectants tend to damage materials and reduce the life of components. Try to select the appropriate disinfectant, and follow the disinfectant manufacturer's instructions and recommendations.
- After disinfection, check the disinfected component for any signs of damage. Replace any damaged component immediately.

WARNINGS!

- After disinfection, rinse any disinfected component in clean water thoroughly, especially components in close contact with the patient such as the mask, headgear, and tube, so as to prevent disinfectant residuals from damaging the skin or respiratory tract or causing allergies.
- The device shall not be serviced or maintained while in use with a patient.
- Sterilization of this device and its components other than recommended is not permitted.

16. Traveling with the Device***CAUTIONS!***

- Empty the water chamber of the humidifier before packing the device for your trip; in order to prevent any remaining water from entering the device.
- Using the device at an incorrect elevation setting could result in airflow pressures higher than the prescribed setting. Always verify the elevation setting when traveling or relocating.
- If the device is used when the atmospheric pressure is out of the stated range (See Section 5), the accuracy of the leakage alert will be affected.

(1) Use the BMC carrying case to carry the device and accessories along with you. Do not put them in your checked baggage.

(2) This device operates on power supplies of 100-240 V and 50/60 Hz, and is suitable for use in any country in the world. No special adjustment is necessary, but you will need to find out the types of the power sockets in your destination. Bring, if necessary, a power socket adaptor which can be bought in electronics stores.

(3) Remember to bring a spare air filter and the emergency documents (filled and signed by your physician) about this device. If you plan to travel by air, remember to bring the multi-language emergency documents about respiratory therapy, in case that the border and customs officers in your destination country inspect the device. With the emergency documents, you can prove to them that it is a medical device.

(4) Security Stations : For convenience at security stations, there is a note on the bottom of the device stating that it is medical equipment. It may be helpful to bring this manual along with you to help security personnel understand the device.

17. Transferring the Device to Another Patient

If the device is transferred to another patient, components in close contact with the previous owner, including the mask, headgear, tube, and air filter, should be cleaned and disinfected to prevent cross-infection.

18. Reordering

Contact your home care provider to order accessories or replacement filters.

The device does not require routine servicing.

- If you notice any unexplained changes in the performance of the device, if it is making unusual or harsh sounds, if it has been dropped or mishandled, if the enclosure is broken, or if water has entered the enclosure, discontinue use. Contact your home care provider.
- If the device malfunctions, contact your home care provider immediately. Never attempt to

open the enclosure of the device. Repairs and adjustments must be performed by BMC-authorized service personnel only. Unauthorized service could cause injury, invalidate the warranty, or result in costly damage.

- If necessary, contact your local authorized dealer or 3B Medical, Inc. for technical support and documents.

19 Technical Support

Please contact 3B directly if you need the circuit diagram of the device and the list of components for certain purposes such as maintenance or connection to other equipment. BMC will provide the circuit diagram and/or other technical documents in whole or in part according to your needs.

20. Disposal

When the device reaches the end of its service life, dispose of the device and packaging in accordance with local laws and regulations.

21. Troubleshooting

The table below lists common problems you may have with the device and possible solutions to those problems. If none of the corrective actions solve the problem, contact your home care provider.

21.1 Common Problems in Patients and Corresponding Solutions

Problem	Possible Cause	Solution(s)
Dry, cold, runny, and blocked nose; having a cold	The nose reacts to the airflow and cold. Due to fast airflow, the air becomes cold, leading to nasal mucosa irritation and subsequent dryness and swelling.	Increase the humidity setting of the humidifier. Contact your physician, and continue treatment unless the physician suggests the opposite.
Dry mouth and throat	Probably because the patient sleeps with his or her mouth open, and the pressurized air goes out via the mouth, leading to nasal and throat dryness.	Use a chin strap to prevent the mouth from opening during sleep, or use a full-face mask. Contact your physician for details.
Eye irritation	The mask size or model may not be correct, or the mask is not positioned correctly, thereby leading to air leakage.	Narrow the distance between the forehead support of the mask and the forehead. Note that adjusting the mask too tight may leave markings on the patient's face. Add additional filling to the mask so it does not leak. Contact your equipment supplier for an appropriate mask. Add additional filling to the mask if necessary.
	Mask cushion (the soft part of the mask) hardens.	Replace the mask or mask cushion.
Facial reddening	The mask is too tight.	Loosen the headgear.
	The distance between the forehead support of the mask and the forehead is not correct.	Try a different distance. The angle and size of the forehead support differ according to the type of masks.
	Wrong mask size	Contract your equipment supplier for a correct-size mask.
	patient is allergic to the materials of the mask.	mask
	When the humidifier is used, the	Turn the humidity setting down, or

Water in mask	humidified air tends to condense in the cold tube and mask if the room temperature is low.	raise the room temperature. Place the tube under the quilt, or use the tube cover. Hang the tube loosely, and the lowest part of the tube should be lower than the patient's head.
Nasal, sinus, or ear pain	Sinus or middle ear inflammation	Contact your physician immediately.
Discomfort due to inability to adapt to the treatment pressure	The patient will feel uncomfortable when the treatment pressure is higher than 13 cmH ₂ O. However, the treatment pressure is determined according to the patient's conditions, and cannot treat sleep apnea if the treatment pressure is set too low.	It takes a maximum of four weeks to adapt to pressurized air. Relax and breathe through the nose. If the problem still exists, contact your physician.
Obstructive sleep apnea symptoms recur.	Probably because the patient sleeps with his or her mouth open, and the pressurized air goes out via the mouth, leading to blockage in the respiratory tract.	Use a chin strap to prevent the mouth from opening during sleep, or use a full-face mask. Contact your physician for details.
The device is too noisy.	The tube is not connected properly.	Reconnect the tube properly.
Air delivered from the device is abnormally hot.	The air inlet of the device may be partially blocked, leading to insufficient airflow into the device.	Clean or replace the air filter (see 15.4 Cleaning the Air Filter), and clean the air inlet.
		Things. Place the device in an area where air flows freely, and make sure the device is at least 20 centimeters away from the wall, curtain, or other things.

21.2 Common Problems in the Device and Corresponding Solutions

Problem	Possible Cause	Solution(s)
The device does not work when it is turned on.	The Auto On/Off feature is enabled	Take a few deep breaths with the mask on, and the device will start automatically.
	Power is not connected properly.	Ensure that the power cord, power adapter, and the device are connected properly.
	There is no voltage.	Check whether a power outage occurs by turning on a light or other means. If you are sure the fuse in the device is broken, contact your equipment supplier for repair.
	Cannot find any cause.	Contact your equipment supplier.
The device is working, but the pressure inside the mask differs from the set treatment pressure.	The tube is not connected properly.	Reconnect the tube properly.
	There may be holes in the mask or pressure sensing tube.	Contact your equipment supplier.
	It is a faulty device.	Contact your equipment supplier.
The device produces very low pressures.	The air inlet of the device may be blocked.	Clean or replace the air filter (see 15.4 Cleaning the Air Filter), and clean the air inlet. Make sure the air inlet is unblocked.
	The treatment pressure has been changed accidentally.	Contact your physician.
	When the Ramp feature is enabled, it takes some time for the initial pressure to rise to the treatment pressure. This is normal.	If necessary, disable the Ramp feature, or set the ramp time shorter.
After the device is turned on, the screen displays intermittently, or displays nothing at all.	The operating system of the device needs to be readjusted or restarted.	Unplug the power cord of the device, and re-plug it 20 seconds later.
The device is in standby, and will not start.	The operating system of the device needs to be readjusted or restarted.	Unplug the power cord of the device, and re-plug it 20 seconds later.

22. EMC Requirements

Guidance and manufacturer's declaration - electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The user of the device should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical home or hospital.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical home or hospital.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or from a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	If the pressure deviates more than is indicated in the device specifications, it may be necessary to position the device further from sources of power frequency magnetic fields. The power frequency magnetic field should be measured in the intended installation location to ensure that it is sufficiently low.
Note: U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 Vrms</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3\sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applied.

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

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

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

Recommended separation distances between portable and mobile RF communications equipment and the device

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

Rated maximum output of transmitter W	150kHz~80MHz $d = 1.2\sqrt{P}$	80MHz~800 MHz $d = 1.2\sqrt{P}$	800 MHz~2.5GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

23. Limited Warranty

Limited Warranty

3B Medical, Inc. warrants that the Luna E-20 models will be free of all defects in workmanship and materials, and will perform according to specifications, for a period of two (2) years of sale from the sale of the device.

If the product fails to perform in accordance with the product specifications, 3B Medical, Inc. will repair or replace, at its option, the defective material or part. This warranty does not cover damage caused by accident, misuse, abuse, alteration and other defects not related to material or workmanship.

- 3B will issue an RMA (Return Merchandise Authorization) within 24 hours of receipt of written notification of a failed or defective unit. Failed/defective units must be returned within 30 days of the RMA date.
- This warranty coverage is applicable to all 3B/BMC CPAP, Auto-CPAP and Auto Bi-Level devices.
- The warranty policy does not cover any damages caused as a result of alteration, intentional damage, modification, or unauthorized repair of the device.
- 3B reserves the right to amend this policy at any time.

To exercise the rights under this warranty, contact your local authorized dealer or:

3B Medical, Inc.
21301 US Highway 27 N
Lake Wales, FL 33859
T: (863) 226-6285
F: (863) 226-6284

For additional information, please visit our Patient Portal at:
www.3bproducts.com
icodeconnect.com – Web-based cloud
for report generation and storage
www.bmc-icode.com – Website for iCode data report retrieval



H60 Heated Humidifier

User Manual

The H60 Heated Humidifier is designed only for use with specific Luna E-20A and E-20C Series devices. Do not use the H60 Heated Humidifier with any other devices.

The humidifier moistens the air delivered by the Luna E-20A and E-20C Series devices. It is for use in the home or hospital/ institutional environment.

The H60 Heated Humidifier is only used for single patient and must not be re-used on another person. This is to avoid the risk of cross-infection.

The H60 Heated Humidifier is not intended for use with a patient whose upper airway has been bypassed.

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1. Warning, Caution and Important Tip

WARNING!

Indicate the possibility of injury to the user or operator.

CAUTION!

Indicate the possibility of damage to the device.

IMPORTANT TIP!

Place emphasis on an operating characteristic.

Warnings, Cautions, and Important Tips appear throughout this manual as they apply.

2. Symbols



Operating Instructions



Type BF Applied Part



Class II (Double Insulated)



AC Power



DC Power

IP22 ≥ 12.5 mm Diameter, Dripping (15° tilted)



Hot Surface



Serial Number of the Product



Manufacturer



Authorized Representative in the European Community



European CE Declaration of Conformity



Water Filling Prohibited Here



Water Inlet



Directional Indicator for Removing the Water Inlet Cap



Directional Indicator for Screwing the Water Inlet Cap

3. Features

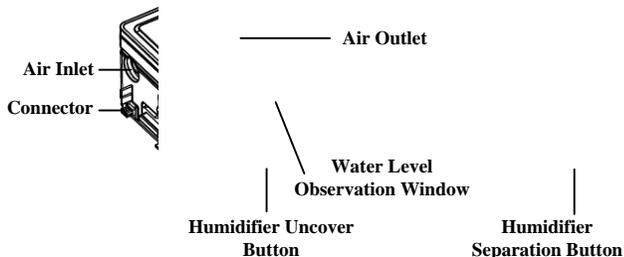


Fig. 3-1

Name	Function
Air Inlet	Connect to the outlet of the main device
Air Outlet	Deliver humidified air to the patient; connect to the air tubing
Connector	Heat the water in the water chamber and detect the temperature
Water Level Observation Window	Observe the water level in the water chamber
Humidifier Uncover Button	Press this button to open the top cover of the humidifier
Humidifier Separation Button	Press this button to separate the humidifier from the main device

4. Daily Use

IMPORTANT!

- Never operate the humidifier if any of its parts are damaged, if it is not working properly, or if the humidifier has been dropped or mishandled. Do not use the humidifier if the water chamber is leaking or damaged in any way. Have any damaged parts replaced before continuing use.
- Read all instructions before using the humidifier.
- Use only with BMC devices whose instructions specify the use of this humidifier.

CAUTIONS!

- This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- Do not operate the device in direct sunlight or near a heating appliance because these conditions can increase the temperature of the air coming out of the device.
- When humidifier is used outside the specified ambient temperature range or humidity range, the performance of humidifier will be compromised.

- U.S. federal law restricts this device to sale by or on the order of a physician.

WARNINGS!

- Use the humidifier only for its intended use as described in this manual.
- Use only accessories recommended by 3B.

4.1 Connecting, Separating the Humidifier and Main Device

4.1.1 Connecting the Humidifier to the Main Device

Remove the shield from the main device, following the steps below:

- (1) Overturn the main device and find the buckle slot at the bottom of the main device, as shown in Fig.4-1.
- (2) Remove the shield by inserting a flat tool into the buckle slot.

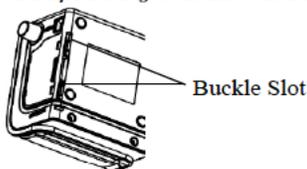


Fig. 4-1

After the shield is removed, place the humidifier and main device near each other as shown in Fig.4-2. The air outlet of the main device should be targeted to the inlet of the humidifier. Push the two devices together until they click into place. Fig.4-2 shows their positions before and after connection to each other.

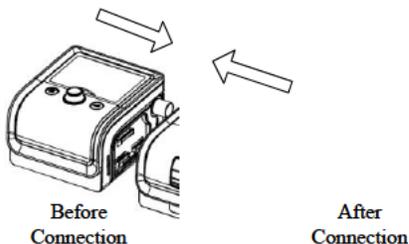


Fig. 4-2

CAUTION!

- When the main device delivers air and the humidity setting is adjusted, if the indicator lights of the humidifier do not light up, it may be that the humidifier and main device are not connected correctly.

4.1.2 Separating the Humidifier from the Main Device

Press the **Humidifier Separation Button** on the humidifier and, at the same time, pull the humidifier and main device apart in opposite horizontal directions, as shown in Fig.4-3.

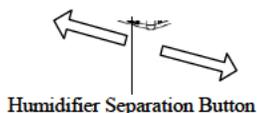


Fig. 4-3

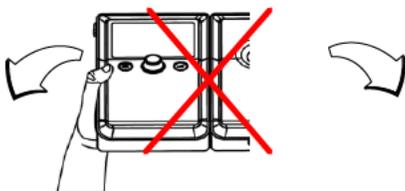


Fig. 4-4

CAUTIONS!

- Do not move the connected unit upwards or downwards while pulling the devices apart (see Fig.4-4). It could cause damage to the devices.
- Place the shield back on the main device when the humidifier is not in use.

4.2 Filling the Water Chamber**4.2.1 Removing the Water Chamber**

Press the **Humidifier Uncover Button** to open the top cover. Hold the front center of the humidifier with your thumb and index finger, and pull the chamber out of the humidifier, as shown in the figure below.

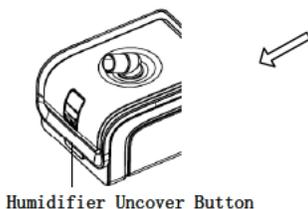


Fig. 4-5

WARNING!

- Turn the device off and allow approximately 15 minutes for the heater plate and water to cool.

4.2.2 Overturning the Water Chamber

Turn the water chamber over so that it is bottom up, as shown in the figure below.

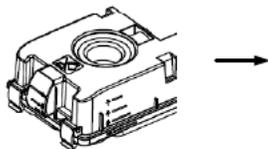


Fig. 4-6

WARNINGS!

- Never touch the heater plate unless the humidifier is unplugged and the plate has cooled down.
- Fill the water chamber only after it is turned over, otherwise the device could be damaged.

4.2.3 Removing the Water Inlet Cap

Turn the water inlet cap counterclockwise so the arrowhead on the cap points to the triangle symbol , and then remove the cap.



Fig. 4-7

4.2.4 Filling Water

Fill the water chamber with approximately 350 ml of water through the water inlet. Make sure that the water does not exceed the maximum water level line. Observe the water level in the water chamber through the Water Level Observation Window.

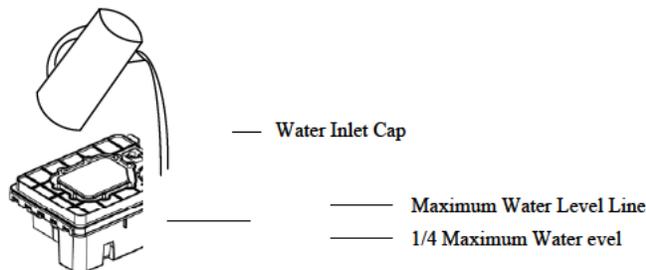


Fig. 4-8

WARNING!

- Every time before treatment, be sure to drain any residual water out of the water chamber, and ensure the maximum water level line is not submerged by water.

CAUTIONS!

- Empty the water chamber when the humidifier is not in use.
- Distilled water is recommended.

4.2.5 Returning the Water Chamber

Put the cap back on the water chamber after it is filled with water. Turn the cap clockwise until the arrowhead on the cap points to the round symbol . Overturn the water chamber and return it to the humidifier.

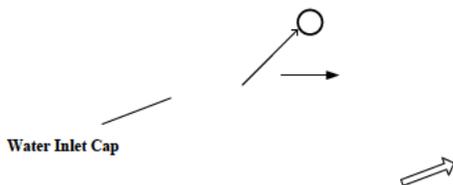


Fig. 4-9

WARNING!

- For safety purposes, the filled humidifier must be placed on a flat surface at a level lower than the patient's head when he or she lies down on a bed, so that the condensation flows back to the water chamber rather than remain in the tubing inhibiting breathing.

CAUTIONS!

- Avoid moving or tilting the humidifier when the water chamber has water in it.
- Do not turn the humidifier on without the water chamber installed.
- Take precautions to protect furniture from water damage.

4.3 Emptying the Water Chamber

- (1) Remove the water chamber according to instructions in 4.2.1.
- (2) **Empty the water chamber:** Separate the main body of the water chamber from the chamber base, and pour any remaining water out of the main body of the water chamber. Undo the **Water Chamber Buckle**, and open the water chamber as shown below.

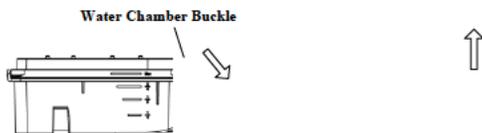


Fig. 4-10

CAUTION!

- Empty and air-dry the water chamber when the humidifier is not in use.
- (3) Assemble the water chamber: Place the main body of the water chamber on a level surface, and then insert the chamber base into the main body of the water chamber and

fasten the **Water Chamber Buckle**, as shown in the figure below.

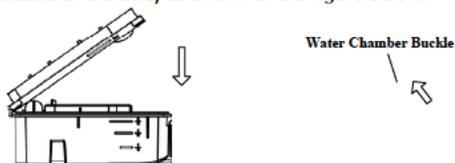


Fig.4-11

4.4 Setting the Humidity Level

After the main device is powered on, turn the **Knob** to turn on or turn off the humidifier and to adjust the humidity level according to instructions on the screen of the main device.

There are five humidity levels available, and the number of blue indicator lights that light up is directly proportional to the humidity level. If none of the indicator lights light up, it means that the humidifier is turned off.

The temperature of the water in the water chamber maintains a constant set level. Three indicator lights light up when the humidity is adjusted to Level 3, as shown in Fig.4-10.

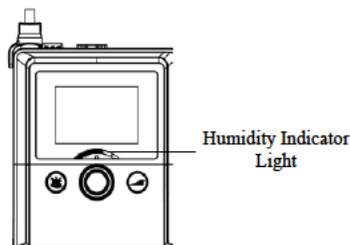


Fig. 4-12

CAUTIONS!

- Generally speaking, the humidity inside the mask is low when the water temperature is low.
- The greater the difference between the temperature inside the air tubing and room temperature is, the more easily condensation occurs inside the tubing.
- If there are only a few condensed water droplets inside the tubing in the morning after therapy, it means that the humidity level is proper; if there are lots of condensed water droplets inside the tubing and/or mask, it means that the humidity level is too high and should be set lower; Nasal dryness means that the humidity level is too low and should be set higher.

WARNING!

- Do not touch the heater plate of the humidifier when it is working, otherwise you may get burned. Turn off the heater plate when the humidifier is not in use.

5. Cleaning

Clean the water chamber before first use of the humidifier or at least once every week. If the humidifier has not been in use for a long time, clean the water chamber before reusing it.

WARNING!

- To avoid electrical shock, disconnect the power cord of the device before cleaning the humidifier. DO NOT immerse the humidifier in any fluids.

CAUTIONS!

- Do not use solutions containing chlorinated lime, chlorine, or aromatic to clean the device and its accessories. Liquid soap containing the humidifying agent or antimicrobials should not be used in cleaning either. These solutions may harden cleaned materials or reduce their life.
- Do not clean or dry the device and its accessories when the temperature is higher than 80°C (176°F). High temperatures could reduce product life.

5.1 Separating the Humidifier Top Cover from its Main Body

Press the **Humidifier Uncover Button** to lift and open the top cover of the humidifier. Continue to lift the top cover until it separates completely from the main body of the humidifier, as shown in the figure below.

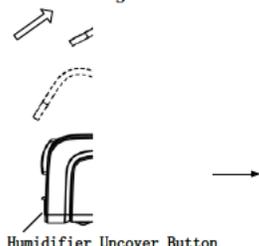


Fig. 5-1

5.2 Removing the Water Chamber

Pull the water chamber out of the main body of the humidifier horizontally, as shown in the figure below.

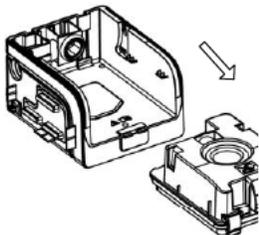


Fig. 5-2

5.3 Detaching the Air-intake Assembly

After the water chamber is removed, detach the **air-intake assembly** from the main body of the humidifier by pulling it upwards, as shown in the figure below.

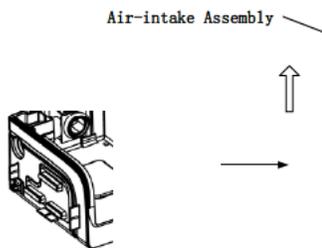


Fig. 5-3

5.4 Cleaning the Water Chamber

WARNINGS!

- Emptying and cleaning the water chamber daily will help prevent mold and bacteria growth.
- Allow the water in the chamber to cool down to room temperature before removing it from the humidifier.

CAUTIONS!

- Clean the water chamber only after the water in it cools. Make sure that no water enters the main device.
- After cleaning, rinse all parts thoroughly in clean water to make sure that no washing liquid is left; then wipe all parts dry with a lint-free cloth, so as to prevent calcareous accumulations.
- Inspect the water chamber for any leak or damage. Replace the water chamber if any damage is present.

(1) Opening the Water Chamber: Undo the **water chamber buckle** and then open the water chamber.

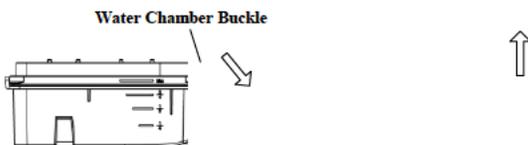


Fig. 5-4

(2) Cleaning the Water Chamber: Wash the two parts of the water chamber, as shown in

Fig.5-2. You may also clean them with a scouring pad (dip the scouring pad in washing liquid if necessary), rinse them thoroughly, and then wipe them dry with a soft cloth.

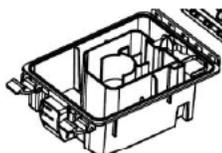


Fig. 5-5

(3) Assembling the Water Chamber: Place the two parts of the water chamber together as shown in Fig.5-6. Press hard until they click into place.

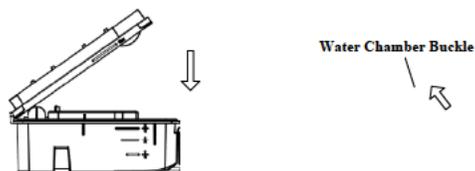


Fig. 5-6

5.5 Cleaning the Air-intake Assembly

First remove the sealing elements from the air-intake assembly, and then clean the air intake and sealing elements separately with running water, as shown in the figure below. They can also be cleaned with a scouring pad (dip the pad in mild scrubbing solutions if necessary), and then rinsed thoroughly. Wipe the air intake with soft cloth, and allow the sealing elements to air dry.

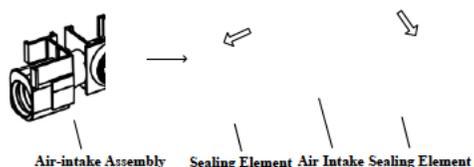


Fig. 5-7

5.6 Cleaning the top cover and main body of the humidifier

Clean the top cover and main body of the humidifier separately with running water, as shown in the figure below. They can also be cleaned with a scouring pad (dip the pad in mild

scrubbing solutions if necessary), then rinsed thoroughly, and at last wiped with soft cloth.

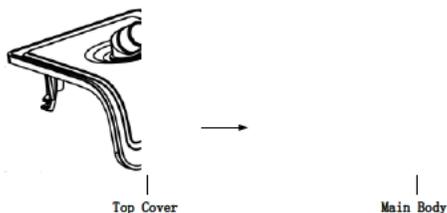


Fig. 5-8

5.7 Reassembling the Humidifier

(1) Set up the air-intake assembly: First install the sealing elements to the air intake, as shown in the figure below.

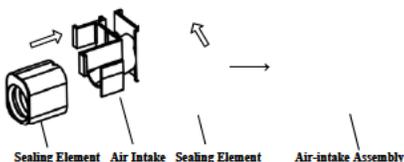


Fig. 5-9

(2) Then install the air-intake assembly back to the main body of the humidifier, as shown in the figure below.

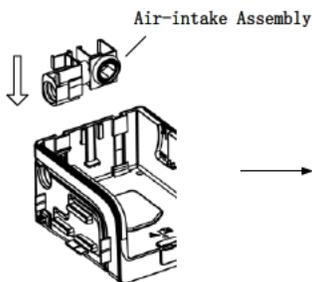


Fig. 5-10

(3) Return the water chamber to the main body of the humidifier, as shown in the figure below.

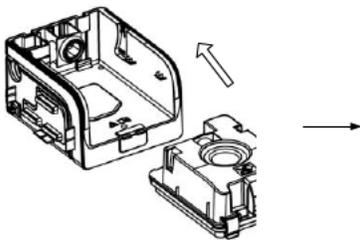


Fig. 5-11

(4) Connect the top cover and main body of the humidifier properly, as shown in the figure below.

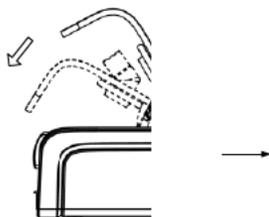


Fig. 5-12

6. Disinfection

Generally speaking, if you have strictly followed the above cleaning instructions, you do not have to disinfect the humidifier. If the device is contaminated or used in clinical trials, you may purchase disinfectants from a pharmacist to disinfect the water chamber.

Disinfection of Humidifier Water Chamber

Prior to disinfection, clean the water chamber according to Section 5.4 "Cleaning the Water Chamber." The disinfection methods are as follows:

- (1) Heat disinfection: Disinfect the water chamber by immersing it in tap water at $75^{\circ}\text{C}\pm 2^{\circ}\text{C}$ for 30 minutes.
- (2) Use mild disinfectants.

CAUTIONS!

- Disinfectants tend to damage materials and reduce the life of components. Try to select the appropriate disinfectant, and follow the disinfectant manufacturer's instructions and recommendations.
- After disinfection, check the disinfected component for any signs of damage. Replace any damaged component immediately.

WARNINGS!

- After disinfection, rinse any disinfected component in clean water thoroughly, especially components in close contact with the patient such as the mask, headgear, and tube, so as to prevent disinfectant residuals from damaging the skin or respiratory tract or causing allergies.
- The device shall not be serviced or maintained while in use with a patient.
- Sterilization of this device and its components other than recommended is not permitted.

7. Service

The humidifier does not require routine servicing.

If the humidifier malfunctions, contact your home care provider immediately. Never attempt to open the humidifier's enclosure. If necessary, contact your local authorized dealer or 3B Medical, Inc. for technical support and documents.

8. Specifications***Size***

Dimensions: 120 × 196 × 134 mm

Weight: < 1 kg

Water Capacity: 350 ml at recommended water level

Product Use, Transport and Storage

	Operation	Transport and Storage
Temperature:	5 to 35°C (41°F to 95°F)	-25 to 70°C (-13°F to 158°F)
Humidity:	15 to 93% Non-condensing	15 to ≤ 93% Non-condensing
Atmospheric Pressure:	760 to 1060 hPa	760 to 1060 hPa

Power Requirements (when the heated humidifier is used with the main device.)

100–240 V AC, 50/60 Hz, 2.0 A max.

Type of Protection Against Electric Shock

Class II Equipment

Degree of Protection Against Electric Shock

Type BF Applied Part

Degree of Protection Against Ingress of Water

IP22

Heater Settings

1 to 5 (95 to 167°F / 35 to 75°C)

Maximum Operating Pressure

30 cmH₂O

Pressure Drop with Humidifier

<0.4 cmH₂O at 60 LPM flow

Humidifier Performance

Humidity Output: No less than 10 mg H₂O / L

Environmental Conditions: Maximum airflow, 35°C, 15% relative humidity

Maximum Delivered Gas Temperature

<43°C

The Form and the Dimensions of the Patient Connection Port

The 22 mm conical air outlet complies with ISO 5356-1

9. Disposal

When necessary, dispose of the device and accessories in accordance with local laws and regulations.

10. Traveling With the System

Packing the System

- (1) Remove the water chamber and pour out all water.
- (2) Return the empty water chamber to the humidifier.
- (3) Put the humidifier in your carry-on bag.

When traveling, the optional carrying case is for carry-on luggage only. The carrying case will not protect the humidifier if it is put through checked baggage.

Security Stations

For ease at security stations, there is a note on the bottom of the humidifier stating that it is medical equipment. It may be helpful to bring this manual along with you for security personnel.

11. EMC Requirements

Guidance and manufacturer's declaration - electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The user of the device should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The device is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD)	±6 kV contact	±6 kV contact	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
IEC 61000-4-2	±8 kV air	±8 kV air	
Electrical fast transient/burst	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical home or hospital.
IEC 61000-4-4	±1 kV for input/output lines	±1 kV for input/output lines	

Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical home or hospital.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or from a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	If the pressure deviates more than is indicated in the device specification, it may be necessary to position the device further from sources of power frequency magnetic fields. The power frequency magnetic field should be measured in the intended installation location to ensure that it is sufficiently low.
Note: U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80	3 Vrms	Portable and mobile RF communications equipment should

<p>Radiated RF IEC 61000-4-3</p>	<p>MHz 3 V/m 80 MHz to 2.5 GHz</p>	<p>3 V/m</p>	<p>be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d=1.2\sqrt{P}$ $d=1.2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d=2.3\sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>Note 1: At 80 MHz and 800 MHz, the higher frequency range applied.</p> <p>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.</p>			

Recommended separation distances between portable and mobile RF communications equipment and the device

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

Rated maximum output of transmitter W	150kHz~80MHz $d=1.2\sqrt{P}$	80MHz~800 MHz $d=1.2\sqrt{P}$	800 MHz~2.5GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

12. Warranty

Limited Warranty

3B Medical, Inc. warrants that the H60 heated humidifier model will be free of all defects in workmanship and materials, and will perform according to specifications, for a period of two (2) years of sale from the sale of the device.

If the product fails to perform in accordance with the product specifications, 3B Medical, Inc. will repair or replace, at its option, the defective material or part. This warranty does not cover damage caused by accident, misuse, abuse, alteration and other defects not related to material or workmanship.

- 3B will issue an RMA (Return Merchandise Authorization) within 24 hours of receipt of written notification of a failed or defective unit. Failed/defective units must be returned within 30 days of the RMA date.
- This warranty coverage is applicable to all 3B/BMC CPAP, Auto-CPAP, Auto Bi-Level devices and H60 heated humidifiers.
- The warranty policy does not cover any damages caused as a result of alteration, intentional damage, modification, or unauthorized repair of the device.
- 3B reserves the right to amend this policy at any time.

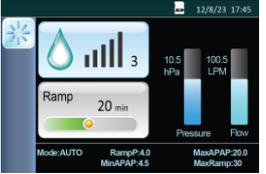
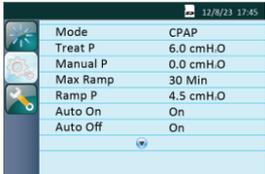
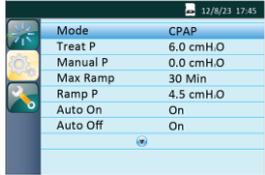
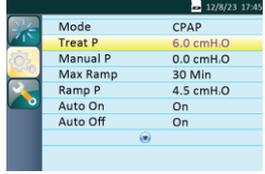
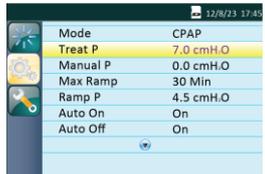
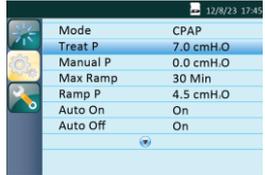
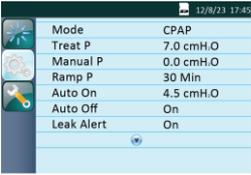
To exercise the rights under this warranty, contact your local authorized dealer or:

3B Medical, Inc.
21301 US Highway 27 N
Lake Wales, FL 33859
T: (863) 226-6285
F: (863) 226-6284

For additional information, please visit our Patient Portal at:
www.3bproducts.com
icodeconnect.com – Web-based cloud
for report generation and storage
www.bmc-icode.com – Website for iCode data report retrieval

E-20 System Clinician Menu Settings

1. Steps to Navigating the Clinician Menu

<p>A. Accessing the Main Interface</p> <p>Connect the power cord and power adapter properly. The screen displays the Main Interface shown in Fig.1-1 (only applies to E-20C-H-O, E-20A-H-O), or the Main Interface shown in Fig.1-2 (only applies to E-20AJ-H-O).</p>	  <p>Fig.1-1</p> <p>Fig.1-2</p>
<p>B. Bringing up the Initial Setup Interface</p> <p>From the Main Interface shown in Fig.1-1 or Fig.1-2, or when the device is delivering air, press and hold the Knob and Ramp Button for five seconds. The screen displays the Initial Setup Interface of the Maintenance Menu, as shown in Fig.1-3.</p> <p>The first icon on the left side of the screen indicates the Main Interface, the second icon indicates the Maintenance Menu, and the third icon indicates the Service Menu. As you turn the Knob, the cursor switches among the three icons, and the menu displayed on the screen changes accordingly.</p>	 <p>Fig.1-3</p>
<p>C. Accessing the Setup Interface</p> <p>When the cursor is on the icon, the screen displays the Setup Interface of the Maintenance Menu. Access the Setup Interface by pressing the Knob. The first option (Mode) on the Setup Interface is then displayed in blue, as shown in Fig.1-4.</p>	 <p>Fig.1-4</p>
<p>D. Selecting Options</p> <p>As you turn the Knob clockwise, the cursor moves downwards from one option to another. As you turn it counterclockwise, the cursor moves upwards. When the cursor is on a certain option, press the Knob, and the option is then displayed in yellow, meaning that the option can now be adjusted, as shown by the Treat P option in Fig.1-5.</p>	 <p>Fig.1-5</p>
<p>E. Adjusting Options</p> <p>Adjust the option by turning the Knob. As shown in Fig.1-6, the Treat P option is selected. Turn the Knob to adjust the option. At this moment, the Treat P option is still displayed in yellow.</p>	 <p>Fig.1-6</p>
<p>F. Confirming Adjustments</p> <p>Confirm your adjustment to an option by pressing the Knob. The option is then displayed in blue, as shown in Fig.1-7.</p>	 <p>Fig.1-7</p>
<p>G. Turning Pages</p> <p>When the cursor is on Auto Off, the last option shown in Fig.1-7, the remaining options will appear on a new page if you continue to turn the Knob clockwise, as shown in Fig.1-8.</p> <p><i>Note: are page turning symbols.</i></p>	 <p>Fig.1-8</p>
<p>H. Returning to the Initial Setup Interface</p> <p>Move the cursor to the Back option by turning the Knob, as shown in Fig.1-9.</p> <p>Press the Knob. The cursor jumps to the second icon on the left side of the screen, and the icon is then displayed in blue. The screen displays the Initial Setup Interface of the Maintenance Menu, as shown in Fig.1-10.</p>	  <p>Fig.1-9</p> <p>Fig.1-10</p>

I. Exiting the Maintenance Menu

Move the cursor to the **Home** option by turning **the Knob**, as shown in Fig.1-11.

Press **the Knob** to exit the Maintenance Menu. The screen will display the Main Interface shown in Fig.1-1 or Fig.1-2.

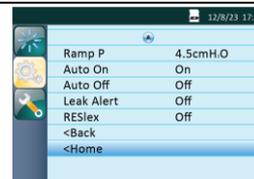


Fig.1-11

2. Steps to Navigating the Service Menu

To navigate the Service Menu, you can refer to steps A-I to navigating the Maintenance Menu, namely bringing up the Initial Setup Interface, accessing the Setup Interface, selecting options, adjusting options, confirming adjustments, turning pages, returning to the Initial Setup Interface, and exiting the Service Menu. These steps are similar for the Maintenance and Service menus. The Initial Setup Interface of the Service Menu is shown in Fig.1-12.



Fig.1-12

3. Description of Maintenance Menu Settings

Mode			Range	Description
CPAP	Titration	AUTO		
Treat P	Treat P	—	4.0-20.0 cmH ₂ O	This pressure is the fixed treatment pressure after ramp time. As you turn the Knob to the nearest point, the numbering increases or decreases by 0.5 cmH ₂ O. The default setting is " 6.0 cmH₂O. "
—	—	Min APAP	4.0-20.0 cmH ₂ O	As you turn the Knob to the nearest point, the numbering increases or decreases by 0.5 cmH ₂ O. The default setting is " 6.0 cmH₂O. "
—	Min TPAP	—	4.0-20.0 cmH ₂ O	As you turn the Knob to the nearest point, the numbering increases or decreases by 0.5 cmH ₂ O. The default setting is " 6.0 cmH₂O. "
Manual P	—	—	0.0-2.0 cmH ₂ O	This feature allows the patient to adjust the treatment pressure within a limited range with the consent of the physician. As you turn the Knob to the nearest point, the numbering increases or decreases by 0.5 cmH ₂ O. The default setting is " 0.0 cmH₂O. "

Max Ramp	Max Ramp	Max Ramp	0-60 min	The ramp time is between 0 and 60 minutes. As you turn the Knob to the nearest point, the numbering increases or decreases by five minutes. The default setting is " 30 minutes. "
Ramp P	—	Ramp P	4.0-20.0 cmH ₂ O	As you turn the Knob to the nearest point, the numbering increases or decreases by 0.5 cmH ₂ O. The default setting is " 4.0 cmH₂O. "
—	—	Max APAP	4.0-20.0 cmH ₂ O	As you turn the Knob to the nearest point, the numbering increases or decreases by 0.5 cmH ₂ O. The default setting is " 15.0 cmH₂O. "
—	Max TPAP	—	4.0-20.0 cmH ₂ O	As you turn the Knob to the nearest point, the numbering increases or decreases by 0.5 cmH ₂ O. The default setting is " 15.0 cmH₂O. "
Auto On	Auto On	Auto On	On/Off	This feature enables the device to start automatically and deliver air at a preset pressure after the patient takes a few deep breaths with the mask on. Turn the Knob to change the setting of this feature. The default setting is " On. "
Auto Off	Auto Off	Auto Off	On/Off	This feature enables the device to automatically discontinue the therapy and shut off when the mask is removed. Turn the Knob to change the setting of this feature. The default setting is " Off. "
Leak Alert	Leak Alert	Leak Alert	On/Off	This feature enables the device to raise an audible alert when the mask falls off the patient's face accidentally. This feature is available only when Auto Off is disabled. Turn the Knob to change the setting of this feature. The default setting is " Off. "
RESlex	RESlex	RESlex	Patient, Off, 1-3	This feature enables the device to automatically detect the patient's respiratory rhythm and reduce pressure in the mask during expiration, so as to make the patient more comfortable. Only when the RESlex option is set to "Patient", the option will appear in the Patient Menu. If this option is set to "Off" or "1-3", it will not appear in the Patient Menu. Turn the Knob to change the setting of this option. The default setting is " Off. "

4. Description of Service Menu Settings

Options	Range	Description
Filter	On/Off	This feature alerts the patient to replace the air filter. The default setting is " Off. "
Unit	hPa/cmH ₂ O	Choose to express the pressure in hPa or cmH ₂ O. The default setting is " cmH₂O. "
Time Format	12-hour/24-hour	Turn the Knob to choose between the two time formats. The default setting is " 12-hour. "
Date Format	yy-mm-dd / mm-dd-yy / dd-mm-yy	Turn the Knob to choose among three date formats. The default setting is " mm-dd-yy. "
Backlight	Auto/On	The backlight of the LCD screen can be set to "Auto" or "On." Turn the Knob to choose between the two modes. If it is set to "Auto," the backlight will turn off automatically after two minutes of inactivity. If it is set to "On," the backlight will always be on. The default setting is " Auto. "
Run Time	—	Show the actual total operation time of the device.
P Cal.	Start P Cal.	Start pressure calibration
Mask Test	Start Mask Test	Measure mask leakage, and classify non-BMC masks as A, B, or C.
Language	English/Español/Português/ Deutsch/中文(简体) /Français/Polski/Italiano/Türkçe/ Русский	Turn the Knob to choose among the ten languages available. The language pack is stored on the SD card, and the Language option only works when the SD card is inserted into the device. The default setting is " English. "

Auto CPAP System

Model: E-20AJ-H-O

AC 100-240V, 50/60Hz, Max 2A

SN E24-----



IP22



BMC Medical Co., Ltd.

Made in China

3BTM

3B Medical, Inc.

21301 US Highway 27 N

Lake Wales, FL 33859

Email: www.3Bproducts.com

RxOnly

CE 0123

Auto CPAP System

Model: E-20AJ-H-O

SN E24-----



RxOnly

CE 0123

Gross Weight: --- kg

Dimensions: 355X225X270 mm

Storage Temp: -25~70 °C

Humidity: Up to 93%, non-condensing



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Lake Wales, FL 33859

Email: www.3Bproducts.com

Auto CPAP System

Model: E-20A-H-O

AC 100-240V, 50/60Hz, Max 2A

SN E23-----



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RxOnly

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Auto CPAP System

Model: E-20A-H-O

SN E23-----



RxOnly

CE 0123

Gross Weight: --- kg

Dimensions: 355X225X270 mm

Storage Temp: -25~70 °C

Humidity: Up to 93%, non-condensing



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CPAP System

Model: E-20C-H-O

AC 100-240V, 50/60Hz, Max 2A

IP22



SN E21-----



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RxOnly

CE 0123

CPAP System

Model: E-20C-H-O

RxOnly

SN E21-----



CE 0123

Gross Weight: --- kg

Dimensions: 355X225X270 mm

Storage Temp: -25~70 °C

Humidity: Up to 93%, non-condensing



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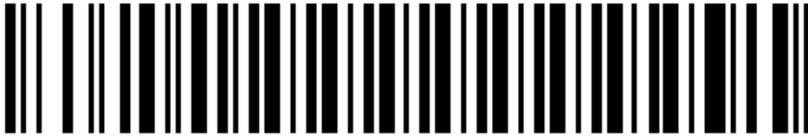
Heated Humidifier

Model: H60

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Heated Humidifier

Model: H60

RxOnly

SN H21-----



CE 0123

Gross Weight: --- kg

Dimensions: 355X225X270 mm

Storage Temp: -25~70 °C

Humidity: Up to 93%, non-condensing



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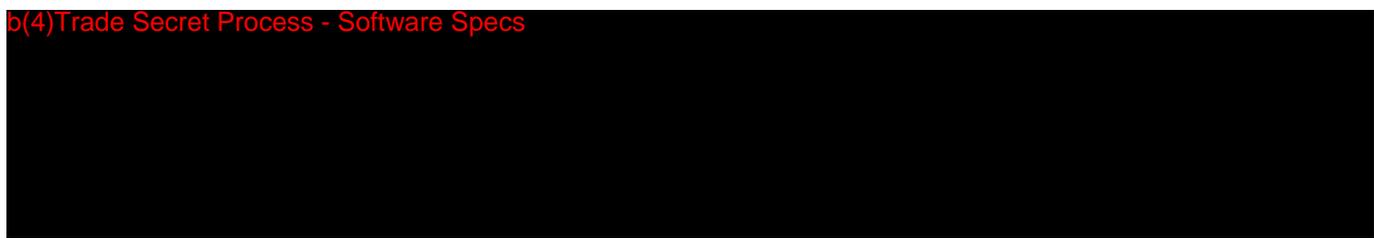
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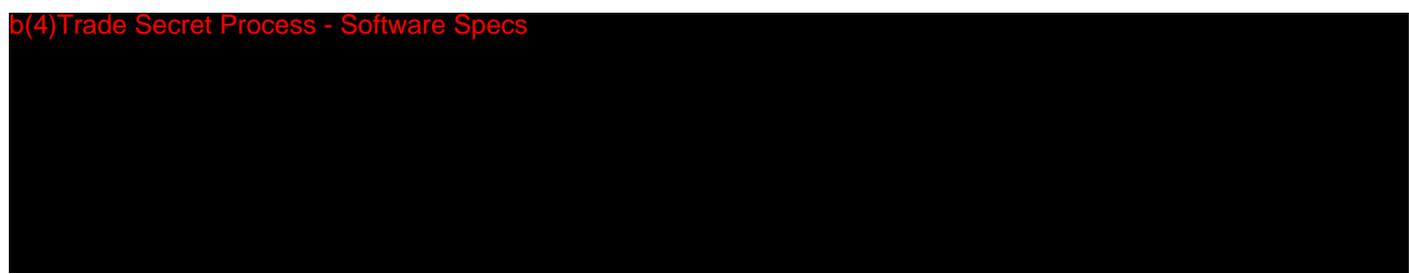
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b(4)Trade Secret Process - Software Specs



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3B™ Medical, Inc.

FDA CDRH DMC

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Received

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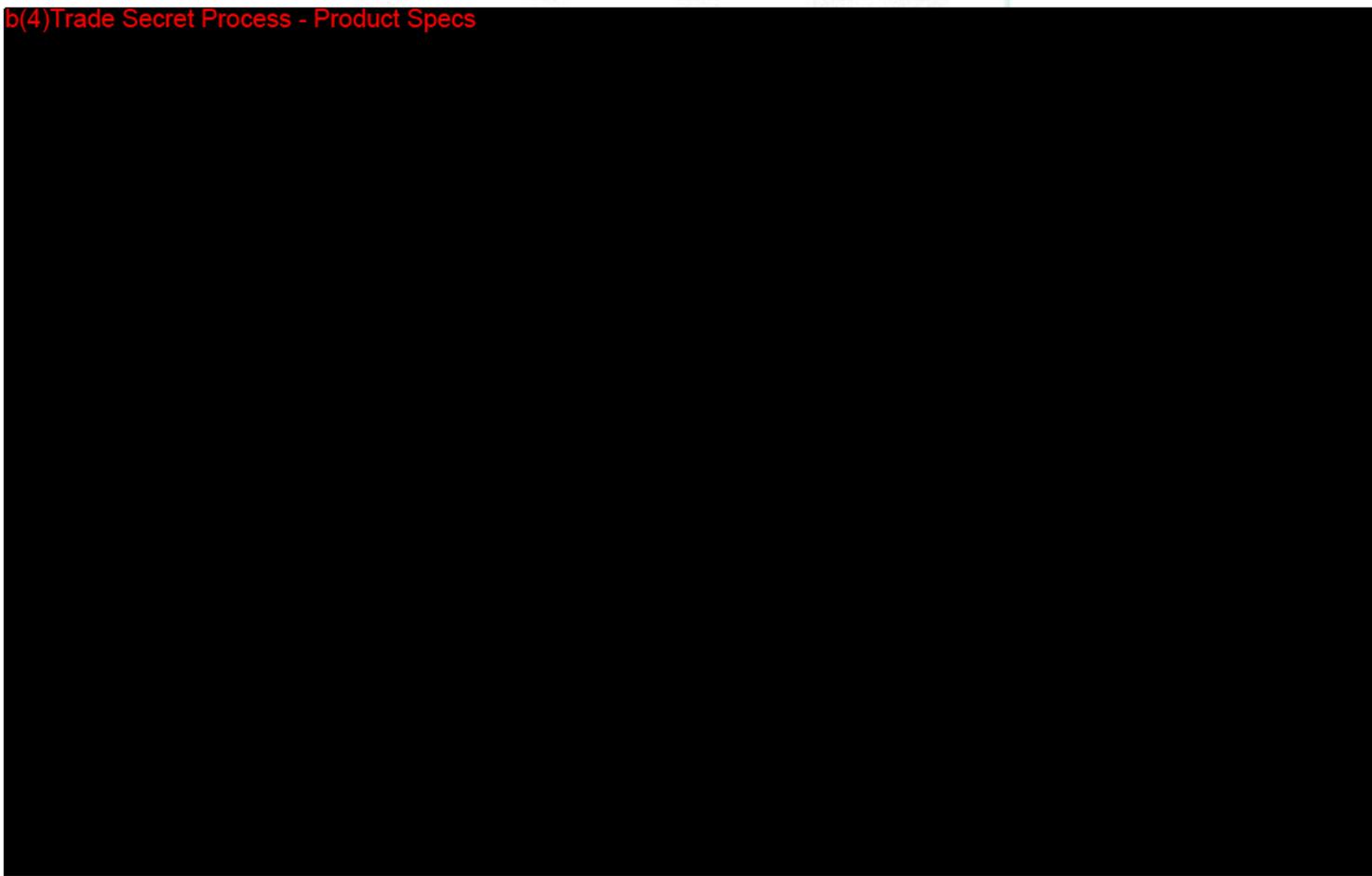
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Att: Ms. Sidra Mirza, BSRC RRT-NPS
FDA/CDRH/ODE/DAGRID
WO66, Room 2457

RE: 510(k) K141770
RESmart GII / Luna CPAP and Auto-CPAP System
Response to RTA Dated

Dear Ms. Mirza:

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1

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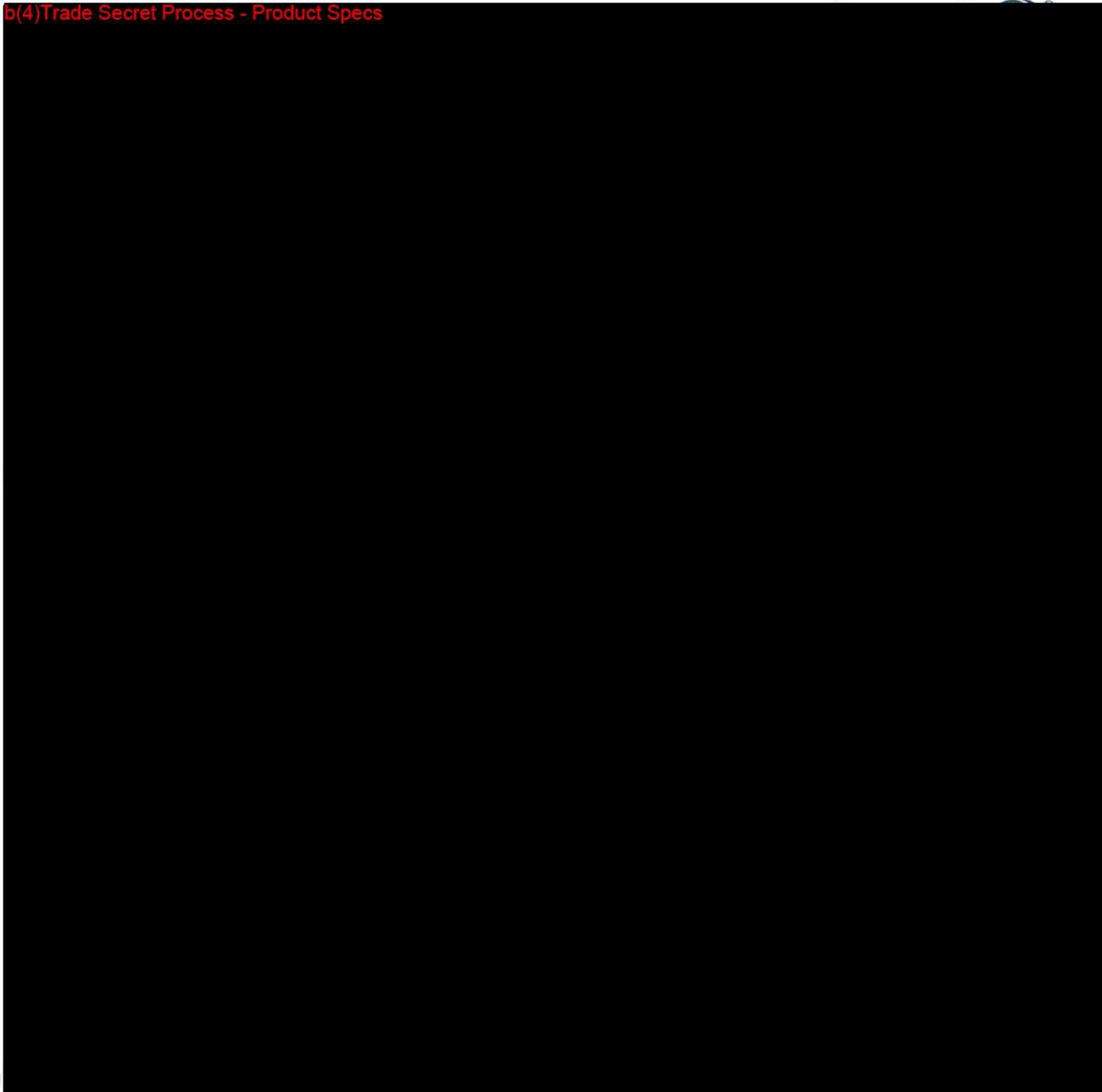
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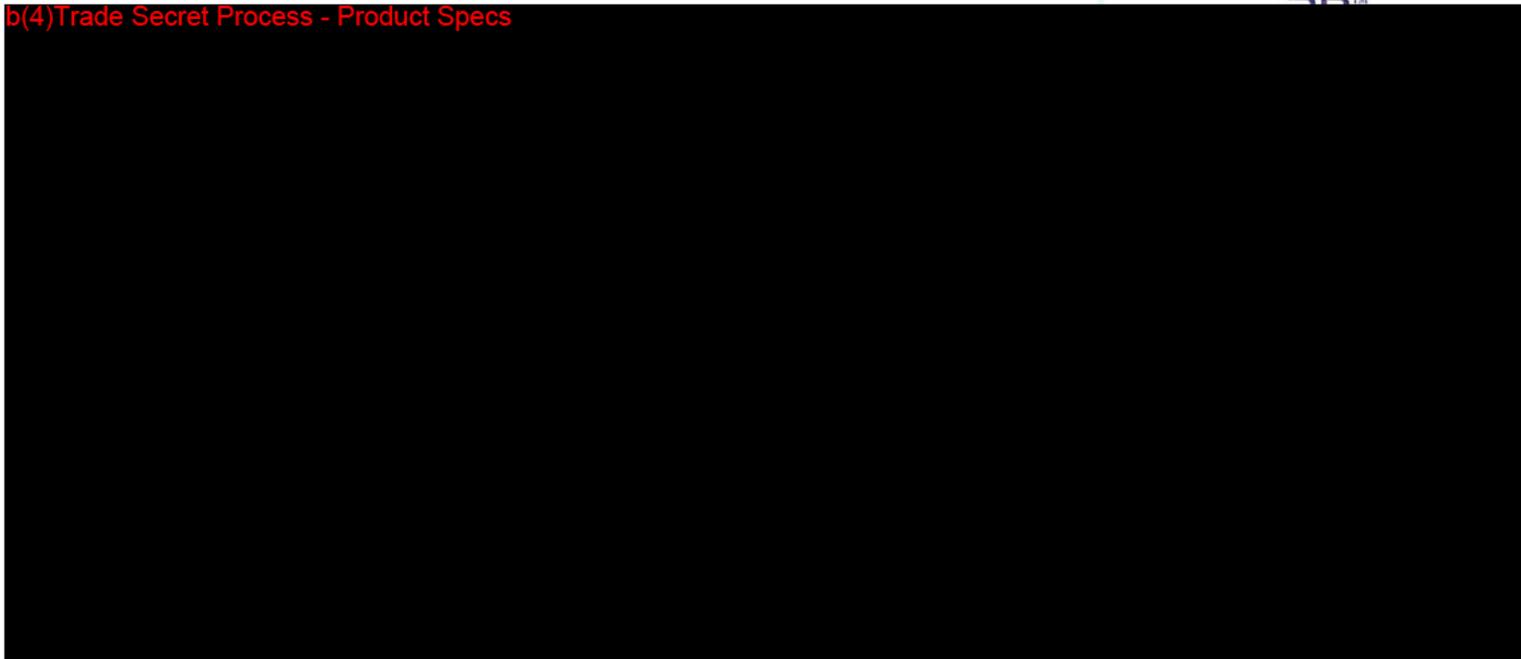
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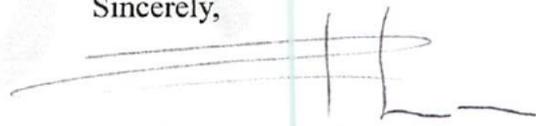
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Sincerely,



Alex Lucio
Vice President

Encl:

Revised User Manual
Revised Risk Management Document

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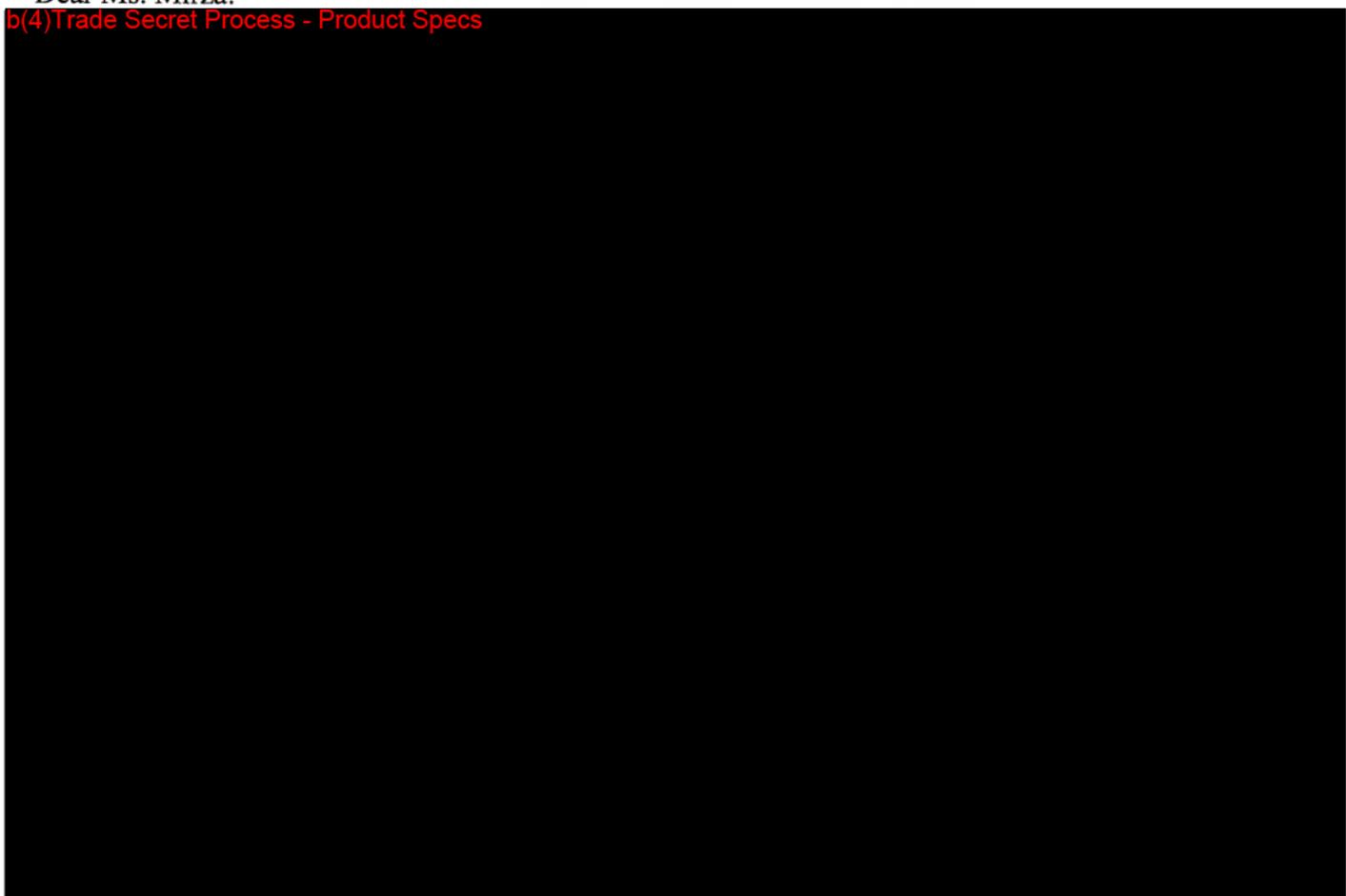


Att: Ms. Sidra Mirza, BSRC RRT-NPS
FDA/CDRH/ODE/DAGRID
WO66, Room 2457

RE: 510(k) K141770
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Response to RTA Dated

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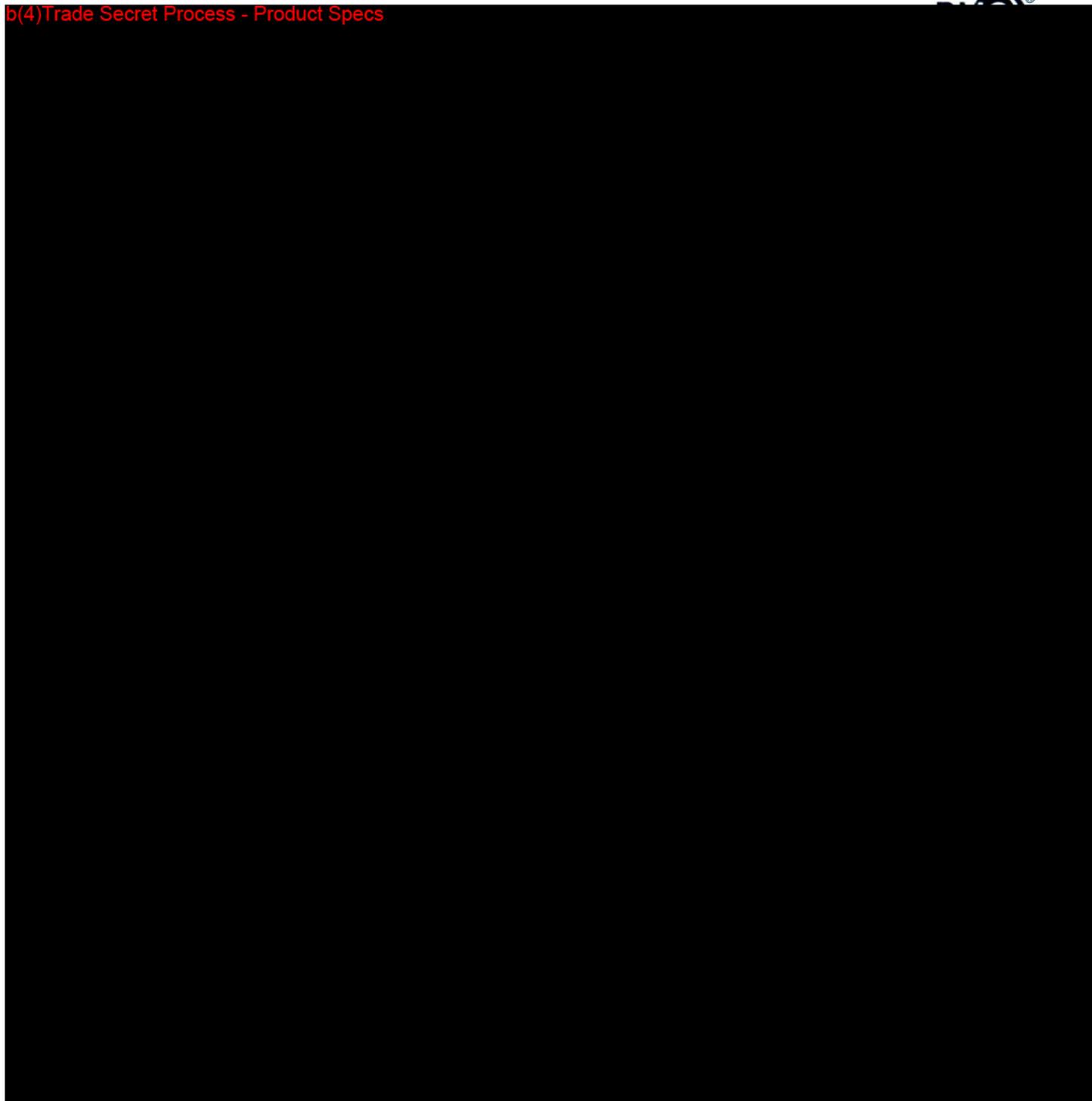
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Sincerely,



Alex Lucio
Vice President

Encl:

Revised User Manual
Revised Risk Management Document

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E-20 System User Manual

E-20C-H-O / E-20A-H-O / E-20AJ-H-O



3BTM
*Solutions in Sleep Therapy*TM
www.3Bproducts.com

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1. Introduction

Thank you for your purchase of the 3B Luna CPAP/Auto-CPAP System. This User Manual will introduce you to your device. Please read it carefully. If, during use, you experience any difficulties or problems, please contact your homecare provider or physician.

2. Symbols

2.1 Control Buttons

	Ramp Button
	Mute Button
	Knob

2.2 Device Symbols

	Operating Instructions
	Type BF Applied Part (mask)
	Class II (Double Insulated)
	AC Power
	DC Power
IP22	≥12.5 mm Diameter, Dripping (15°tilted)
	Hot Surface
	Serial Number of the Product
	Manufacturer
	European CE Declaration of Conformity
	SD Card
	Water Filling Prohibited Here
	Water Inlet
	Directional Indicator for Removing the Water Inlet Cap
	Directional Indicator for Screwing the Water Inlet Cap

3. Warning, Caution and Important Tip

WARNING!

Indicate the possibility of injury to the user or operator.

CAUTION!

Indicate the possibility of damage to the device.

IMPORTANT TIP!

Place emphasis on an operating characteristic.

Warnings, Cautions, and Important Tips appear throughout this manual as they apply.

4. Intended Use

The 3B and BMC CPAP and Auto CPAP Systems are intended to deliver positive pressure for the treatment of Obstructive Sleep Apnea. The optional integrated humidifier is indicated for the humidification and warming of air from the flow generator. These devices are intended for single patient use by prescription in the home or hospital/institutional environment on adult patients.

WARNINGS!

- This device is intended for adult use only.
- This device is not intended for life support.
- The instructions in this manual are not intended to supersede established medical protocols.

CAUTION!

- This device is restricted to sale by or on the order of a physician.
- The device is intended for use by operators trained or experienced in similar equipment.
- The patient is an intended operator.
- Cleaning can be performed by the patient.

IMPORTANT!

- Read and understand the entire user manual before operating this system. If you have any questions concerning the use of this system, contact your home care provider or health care professional.

5. Contraindications

Studies have shown that the following pre-existing conditions may contraindicate the use of positive airway pressure therapy for some patients:

Absolute Contraindications: pneumothorax, mediastinal emphysema; cerebrospinal fluid leak, traumatic brain injury, or pneumocephalus; shock caused by a variety of conditions before treatment; active epistaxis; upper gastrointestinal bleeding before treatment; coma or impaired consciousness making the use of mask during therapy impossible; giant vocal fold polyp, etc.

Relative Contraindications: severe coronary heart disease complicated with left ventricular failure, acute otitis media, excessive respiratory secretions and weak cough, weak spontaneous breathing, nasal or oral tracheal intubation and tracheotomy, severe nasal congestion caused by a variety of conditions, lung bullae, and allergies to breathing masks, etc.

The following side effects may occur during treatment:

- Dryness of the mouth, nose and throat
- Abdominal bloating
- Ear or sinus discomfort
- Eye irritation
- Skin irritation due to the use of a mask
- Chest discomfort

IMPORTANT!

- An irregular sleep schedule, alcohol consumption, obesity, sleeping pills, or sedatives may aggravate your symptoms.

CAUTION!

- Contact your health care professional if symptoms of sleep apnea recur. Contact your health care professional if you have any questions concerning your therapy.

6. Specifications

Device Size

Dimensions: 170 mm × 196 mm × 118 mm, or 290 mm × 196 mm × 134 mm (with the humidifier)

Weight: 1.5 kg, or 2.5 kg (with the humidifier)

Product Use, Transport and Storage

	Operation	Transport and Storage
Temperature:	5°C to 35°C (41°F to 95°F)	-25°C to 70°C (-13°F to 158°F)
Humidity:	15% to 93% Non-condensing	15% to 93% Non-condensing
Atmospheric Pressure:	760-1060 hPa	760-1060 hPa

Mode of Operation

Continuous

Work Mode

For E-20C system: CPAP

For E-20A system: CPAP, AUTO

SD Card

With a capacity ≥ 2 G, the SD card can record patient data and fault information. Furthermore, the language pack stored on the SD card enables you to change the language of the device.

AC Power Consumption

100–240 V AC, 50/60 Hz, 2.0 A max

Type of Protection Against Electric Shock

Class II Equipment

Degree of Protection Against Electric Shock

Type BF Applied Part

Degree of Protection Against Ingress of Water

IP22

Pressure Range

4 to 20 hPa (in 0.5 hPa increments), ≤ 30 hPa under single fault conditions.

Pressure Display Accuracy

±(0.5 hPa + 4%)

Pressure Stability

4 to 20 hPa (±1 hPa)

Ramp

The ramp time ranges from 0 to 60 minutes

Sound Pressure Level

<30 dB, when the device is working at the pressure of 10 hPa.

Sound Power Level

<38 dB, when the device is working at the pressure of 10 hPa.

Maximum Flow

Test Pressure (hPa)	4	9	15	20
Average Flow at the Patient Connection Port (l/min)	80	92	91	96

Air Hose

Length: 6 ft. (1.83 m)

The Form and the Dimensions of the Patient Connection Port

The 22 mm conical air outlet complies with ISO 5356-1

7. Available Therapies

The device delivers the following therapies:

CPAP- Delivers Continuous Positive Airway Pressure; CPAP maintains a constant level of pressure throughout the breathing cycle. If your health care professional has prescribed ramp for you, you can press **the Ramp Button**  to reduce the pressure and then gradually increase the pressure to the therapeutic pressure setting so that you can fall asleep more comfortably.

Auto- Delivers CPAP therapy and provides an air pressure no less than the prescribed one based on the patient's needs.

8. Glossary

Apnea

A condition marked by the cessation of spontaneous breathing.

Auto-CPAP

Adjust CPAP pressure automatically to improve patient comfort based on monitoring of apnea and snoring events.

Auto Off

When this feature is enabled, the device automatically discontinues therapy whenever the mask is removed.

Auto On

When this feature is enabled, the device automatically initiates therapy when you breathe into the mask.

CPAP

Continuous Positive Airway Pressure

iCode

A feature that is intended to give access to compliance and therapy management information. The "iCode" consists of six separate codes displayed in the Patient Menu. iCode I displays sequences of characters, and iCode II displays two-dimensional codes .

LPM

Liters Per Minute

OSA

Obstructive Sleep Apnea

Patient Menu

The display mode in which you can change patient-adjustable device settings, such as the starting pressure for the Ramp feature.

Ramp

A feature that may increase patient comfort when therapy is started. It can reduce pressure and then gradually increase the pressure to the prescription setting so the patient can fall asleep more comfortably.

Reslex

A therapy feature that is enabled by your home care provider to provide pressure relief during exhalation.

Standby State

The state of the device when power is applied but the airflow is turned off.

9. Model

Model	Product Description			
	Product Contents	Work Mode	Size (mm)	Weight
E-20C-H-O	Main device(2.4-inch LCD), Humidifier (H60)	CPAP	290(W)×196(D)×134(H)	2.5 kg
E-20A-H-O	Main device (3.5-inch LCD), Humidifier (H60)	CPAP AUTO	290(W)×196(D)×134(H)	2.5 kg
E-20AJ-H-O	Main device (2.4-inch LCD), Humidifier (H60)		290(W)×196(D)×134(H)	2.5 kg

10. Package Contents

After unpacking the system, make sure you have everything shown here:

No.	Articles	Num.	Notes
1	Main Device	1	
2	Humidifier	1	Optional
3	Shield	1	
4	Air Filter	2	
5	Power Adapter	1	
6	Power Cord	1	
7	SD Card	1	Optional
8	Carrying Case	1	
9	User Manual	1	
10	Quick Operation Manuel	1	

All parts and accessories do not contain latex.
The expected service life of the main device is 5 years.

IMPORTANT!

- If any of the above parts are missing, contact your home care provider.
- Contact your home care provider for additional information on the available accessories of this device. When using optional accessories, always follow the instructions enclosed with the accessories.

WARNING!

- The use of inappropriate masks and accessories may affect the performance of the device and impair the effectiveness of therapy.

11. System Features

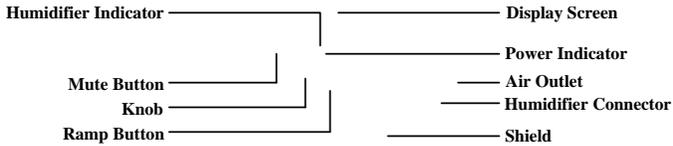


Fig. 11-1

Name	Function
Humidifier Indicator	Indicate the humidity level. There are five levels in total. The number of blue indicator lights that light up is directly proportional to the humidity level. If none of the indicator lights light up, it means the humidifier is turned off.
Mute Button	Press this button to mute the alert. However, if the problem causing the alert is not solved, the alert will sound again two minutes later.
Knob	Start treatment and adjust device settings
Ramp Button	Enable the Ramp feature
Display Screen	Display menus for operation, messages, monitoring data, etc.
Power Indicator	Indicate the power supply status with the green indicator light.
Air Outlet	Deliver pressurized air; connected to the air hose or the air inlet of the humidifier
Humidifier Connector	Provide power to the humidifier which is connected to the main device
Shield	Connect the humidifier to the main device after this shield is removed.

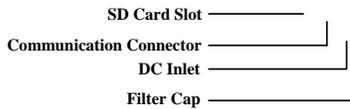


Fig. 11-2

Name	Function
SD Card Slot	Insert the SD card into this slot
Communication Connector	Connected to external equipment
DC Inlet	An inlet for the DC power supply
Air Filter and Filter Cap	Place the cap on the air filter, which is used to filter dust and pollen in the air entering the device.

12. First Time Setup

12.1 Placing the Device

Place the device on a firm, flat surface.

WARNINGS!

- If the device has been dropped or mishandled, if the enclosure is broken, or if water has entered the enclosure, disconnect the power cord and discontinue use. Contact your home care provider immediately.
- If the room temperature is warmer than 95°F (35°C), the airflow produced by the device may exceed 109.4°F (43°C). The room temperature must be kept below 95°F (35°C) while the patient uses the device.

CAUTIONS!

- If the device has been exposed to either very hot or very cold temperatures, allow it to adjust to room temperature (approximately 2 hours) before beginning setup.
- Make sure the device is away from any heating or cooling equipment (e.g., forced air vents, radiators, air conditioners).
- The device is not suitable for use in high humidity environments. Make sure that no water enters the device.
- Make sure that bedding, curtains, or other objects (such as pests) are not blocking or entering the filter or vents of the device.
- Keep pets or children away from the device.
- To avoid explosion, this device must not be used in the presence of flammable gases (e.g. anesthetics).
- Tobacco smoke may cause tar build-up within the device, leading to the

malfunctioning of the device.

- Air must flow freely around the device for it to work properly.

12.2 Installing the Air Filter and Filter Cap

(1) Attach the air filter to the filter cap, as shown in Fig.12-1.

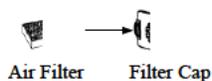


Fig. 12-1

(2) Install the filter cap containing the air filter to the main device, as shown in Fig.12-2.

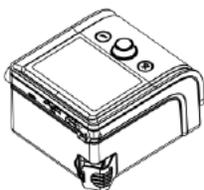


Fig. 12-2

CAUTION!

- The air filter must be in place when the device is operating.
- Installing the air filter and filter cap, device must be unplugged.

12.3 Connecting to Power

- (1) Insert the plug of the power adapter into the DC Inlet on the back of the device;
- (2) Connect the power cord to the power adapter;
- (3) Plug the other end of the power cord into the power outlet.

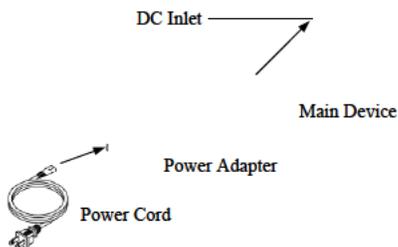


Fig. 12-3

WARNINGS!

- The device is powered on for use when the power cord and power adapter is

connected. The **Knob** turns the blower On/Off.

- Use of the device at an AC voltage beyond the stated range (see Section 6 “AC Power Consumption”) may damage the device or cause device failure

CAUTION!

- Inspect the power cord often for any signs of damage. Replace a damaged cord immediately.

IMPORTANT!

- After interruption and restoration of the power supply, the device will restore its pre-interruption working status automatically.
- To remove AC power, disconnect the power cord from the power outlet.

12.4 Assembling the Air hose and Mask

(1) Connect one end of the air hose to the air outlet of the main device, as shown in Fig. 12-4. If the main device is used with a humidifier, connect one end of the air hose to the air outlet of the humidifier, as shown in Fig. 12-5.

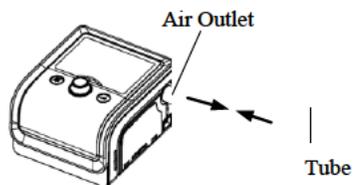


Fig. 12-4

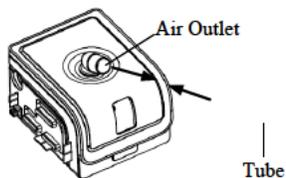


Fig. 12-5

(2) Connect the other end of the air hose to the mask according to the user manual for the mask. Wear the mask.

WARNINGS!

- If you are using a mask with a built-in exhalation port, connect the mask's connector to the air hose.
- If you are using a mask with a separate exhalation port, connect the air hose to the exhalation port. Position the exhalation port so that the vented air is blowing away from your face. Connect the mask's connector to the exhalation port.

- If you are using a full-face mask (a mask covering both your mouth and nose), the mask must be equipped with a safety (entrainment) valve.
- In order to minimize the risk of CO₂ rebreathing, the patient should observe the following instructions:
 - Do not wear the mask for more than a few minutes while the device is not operating.
 - Use only masks with vent holes. Do not block or try to seal the vent holes in the exhalation port.

12.5 Using Oxygen with the Device

Oxygen may be added at the mask connection. Please observe the instructions listed below when using oxygen with the device.

WARNINGS!

- Connect the oxygen air hose to the oxygen inlet of the mask.
- The oxygen supply must comply with the local regulations for medical oxygen.
- Turn on the device before turning on the oxygen. Turn off the oxygen before turning off the device. Explanation of Warning: When the device is turned off, but the oxygen flow still exists, oxygen may accumulate within the device's enclosure and pose a fire hazard. Turning off the oxygen before turning off the device will prevent oxygen accumulation in the device and reduce the risk of fire. This warning applies to most CPAP devices.
- Oxygen supports combustion. Keep the device and the oxygen container away from heat, open flames, any oily substances, or other sources of ignition. DO NOT smoke in the area near E-20C / E-20A or the oxygen container.
- Sources of oxygen should be located more than 1 m from the device.

12.6 Inserting the SD Card

Insert the SD card into the SD Card Slot, as shown in Fig.12-6.

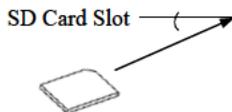


Fig. 12-6

If the SD card is inserted correctly, a symbol indicating correct insertion will appear in the Main Interface on the screen of the device, as shown in Fig.12-7.

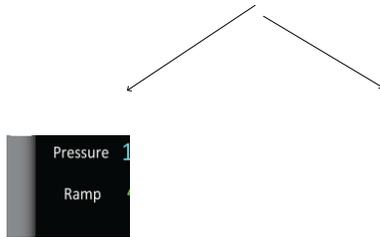


Fig. 12-7

If the SD card is inserted incorrectly or not inserted, a symbol indicating incorrect insertion or no SD card present will appear in the Main Interface on the screen of the device, as shown in Fig.12-8.

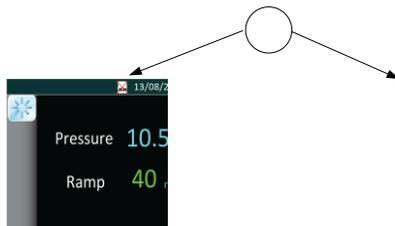


Fig. 12-8

CAUTION!

- To avoid data loss or any damage to the SD card, the SD card can only be removed after the main device stops delivering air.

12.7 Using the H60 Heated Humidifier

The H60 Heated Humidifier is available from your home care provider. The humidifier may reduce nasal dryness and irritation by adding moisture (and heat if applicable) to the airflow. For detailed information about the heated humidifier, please see the user manual for the heated humidifier.

12.8 Starting Treatment

Connect the device to a power outlet, press **the Knob** , and the device will start delivering air.

WARNINGS!

- Be sure to follow your physician's instructions on adjusting the settings! To order any accessories not included with this device, contact your equipment supplier.
- DO NOT connect any ancillary equipment to this device unless recommended by your homecare provider or your physician. If you suffer from chest discomfort,

shortness of breath, stomach bloating, or severe headache when using the device, contact your physician or qualified medical personnel immediately.

13. Routine Use

13.1 Connecting the Air hose

Connect the power cord, power adapter, and air hose properly according to the instructions in the First Time Setup (Chapter 12). Connect the mask and headgear according to the user manual for the mask.

CAUTION!

- Before each use, examine the air hose for any damage or debris. If necessary, clean the air hose to remove the debris. Replace any damaged air hose. Make sure that the mask does not leak.

13.2 Adjusting the Air hose

Lie down on your bed, and adjust the air hose so it is free to move if you turn during sleep. Adjust the mask and headgear until you have a comfortable fit and until there are no airflow leaks into your eyes.

13.3 Turning on the Airflow

Press **the Knob**  to turn on the airflow. The screen will display treatment pressure and other information.

13.4 Heating the Water in the Humidifier

Pay attention to the humidifier indicator lights when using the device with a humidifier. The indicator lights indicate the On/Off state of the humidifier. It is off when all indicator lights go out.

CAUTION!

- Observe the water level of the water chamber before using the humidifier. Make sure there is sufficient water in the water chamber, and avoid heating the humidifier with an empty water chamber.

13.5 Using the Ramp Button

Every time **the Ramp Button**  is pressed, the pressure will drop to the initial pressure, and then gradually rise to the prescribed treatment pressure according to the preset ramp time, so as to make the patient fall asleep easily. The screen displays a real-time countdown of the remaining ramp time in minutes.

CAUTIONS!

- You can press **the Ramp Button**  as often as you wish during sleep.

- The ramp feature is not prescribed for all users.

13.6 Turning the Device Off

Take off the mask and headgear, press and hold **the Knob** for two seconds, and the device will stop delivering air. Disconnect the power cord from the power outlet to power off the device.

CAUTIONS!

- Do not position the device so that it is difficult to operate the disconnection device.
- To isolate the device from the supply mains, disconnect the plug.

14. Navigating the Patient Menu

14.1 Steps to Navigating the Patient Menu

14.1.1 Accessing the Main Interface

Connect the power cord and power adapter properly. The screen displays the Main Interface shown in Fig.14-1 (applies to E-20A-H-O), or the Main Interface shown in Fig.14-2 (applies to E-20C-H-O and E-20AJ-H-O).

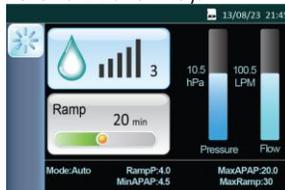


Fig. 14-1



Fig. 14-2

14.1.2 Bringing up the Initial Setup Interface

From the Main Interface shown in Fig.14-1 or Fig.14-2, or when the device delivers air, press and hold **the Ramp Button** for three seconds. The screen displays the Initial Setup Interface of the Patient Menu, as shown in Fig.14-3.



Fig. 14-3

The first icon  on the left side of the screen indicates the Main Interface, and the second icon  indicates the Initial Setup Interface. As you turn **the Knob** , the cursor switches between the two icons, and the interface displayed on the screen changes accordingly.

14.1.3 Accessing the Setup Interface

When the cursor is on the icon , the screen displays the Setup Interface. Access the Setup Interface by pressing **the Knob** . The first option on the Setup Interface is then displayed in blue, as shown in Fig.14-4.



Fig. 14-4

14.1.4 Selecting Options

As you turn **the Knob**  clockwise, the cursor moves downwards from one option to another. As you turn it counterclockwise, the cursor moves upwards. When the cursor is on a certain option, press **the Knob** , and the option is then displayed in yellow, meaning that the option can now be adjusted, as shown by the **Humidifier** option in Fig.14-5.



Fig. 14-5

14.1.5 Adjusting Options

Adjust the option by turning **the Knob** . As shown in Fig.14-5, the **Humidifier** option is selected. As you turn **the Knob**  clockwise, the numbering increases, indicating a higher humidity level. As you turn **the Knob**  counterclockwise, the numbering decreases, indicating a lower humidity level. At this moment, the **Humidifier** option is still displayed in yellow, as shown in Fig.14-6.



Fig. 14-6

14.1.6 Confirming Adjustments

Confirm your adjustment to an option by pressing **the Knob**. The option is then displayed in blue, as shown in Fig.14-7.



Fig. 14-7

14.1.7 Turning Pages

When the cursor is on **Mask Type**, the last option shown in Fig.14-7, the remaining options will appear on a new page if you continue to turn **the Knob** clockwise, as shown in Fig.14-8.

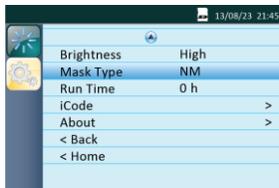


Fig. 14-8

Note: are page turning symbols.

14.1.8 Exiting the Patient Menu

(1) Returning to the Initial Setup Interface

Move the cursor to the **Back** option by turning **the Knob**, as shown in Fig.14-9.

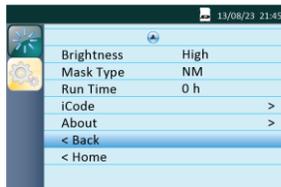


Fig. 14-9

Press **the Knob**, the cursor jumps to the second icon on the left side of the

screen. The screen displays the Initial Setup Interface, as shown in Fig.14-10.



Fig. 14-10

(2) Returning to the Main Interface

Move the cursor to the **Home** option by turning **the Knob**, as shown in Fig.14-11.

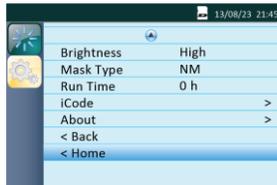


Fig. 14-11

Press **the Knob** to exit the Patient Menu. The screen will display the Main Interface shown in Fig.14-1 or Fig.14-2.

14.2 Options of the Patient Menu and Corresponding Descriptions

Option	Range	Description
Humidifier	Off, 1-5	There are five humidity levels available. As the numbering increases, the humidity rises accordingly. "Off" means the humidifier is turned off. The default setting is "2."
Reslex	Off, 1-3	This feature enables the device to automatically reduce the treatment pressure when the patient exhales, so as to make the user more comfortable. The higher the numbering is, the more pressure the device reduces. "Off" means this feature is disabled. The default setting is "Off."
Ramp Time	0- Max Ramp	In order to increase comfort and help the patient fall asleep easily, the pressure can increase gradually, when the Ramp feature is enabled. The ramp time during which the initial pressure rises to the prescribed treatment pressure can be adjusted. As you turn the Knob to the nearest point, the numbering increases or decreases by five minutes. The default setting is "10 minutes." The screen displays a real-time countdown of the remaining ramp time in minutes.
Delay	On/Off	When the humidifier is on, this feature allows the airflow to continue for about 15 minutes at a low pressure (about 2 hPa) after you press the Knob to discontinue treatment. This will blow off the vapor left in the humidifier to avoid any damage to the device. When this feature is set to "Off," which means it is disabled, the airflow stops delivering air instantly after you press the Knob . The default setting is "Off."
Date	2000-01-01 — 2099-12-31	Setting date by adjusting this option.
Time	—	Setting time by adjusting this option.
Brightness	High/Low	Setting screen brightness by adjusting this option. The default setting is "High."
Mask Type	FM; NM; PM; A, B, C	There are three mask types available, namely FM (full-face mask), NM (nasal mask), and PM (nasal pillow mask). The default mask type is "NM," but the patient can choose other suitable masks as well. When selecting masks other than the above three types of masks, the patient can identify the masks as A, B, or C.
Run Time	0-50000 h	Use Time displays how long has the device been used by the user. The use time can be erased.

iCode	iCode I, iCode II	iCode provides access to the patient's compliance data during a recent time period. The iCode I mode displays data in sequences of characters, and the iCode II mode displays data in two-dimensional codes.
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15. Alert

Alert Message	Description
Power Failure!!!	An audible alert will sound if the device is accidentally disconnected from power when it is delivering air. Note: (1) The alert will not sound if power failure occurs when the device is in standby state. (2) No alert message on the screen during a power failure.
Device Fault!!!	An audible alert will sound if no airflow comes out of the machine; the screen will display " Device Fault!!! "
Leak!!	When the airflow is on, an audible alert will sound if the air leak rate exceeds 150 l/min; the screen will display " Leak!! "
Low Input Voltage!!	If you use a battery rather than an external power adapter to power the device, an audible alert will sound when the battery is low; the screen will display " Low Input Voltage!! "
Humidifier Failure!!	when humidifier is applied, an audible alert will sound when the humidifier fails to work; the screen will display " Humidifier Failure!! "
Please Change Filter!	When the Filter Alert feature is enabled, an audible alert will sound if an air filter has been used for more than six months; the screen will display " Please Change Filter! "
SD Card Full!	The screen will display " SD Card Full! " if the SD card has reached its maximum capacity.
Reinsert SD card!	The screen will display " Reinsert SD card! " if the SD card fails to work

16. Cleaning

WARNINGS!

- Regular cleaning of the device and its accessories is very important for the prevention of respiratory infections.
- To avoid electric shock, always unplug the device before cleaning.
- Use washing liquid that is nontoxic to humans and does not cause allergies in humans.
- Follow the manufacturer's instructions on cleaning the mask and air hose and on determining the frequency of cleaning.
- Before cleaning, check whether the device has been disconnected from the power supply, whether the power cord has been unplugged, and whether the water chamber of the humidifier has cooled down. Make sure the heater plate has cooled down to room temperature, so you do not get burned.
- The device shall not be serviced or maintained while in use with a patient.
- Sterilization of this device and its components other than recommended is not permitted.

CAUTIONS!

- Overheating of the materials could lead to early fatigue of these materials.
- Do not use solutions containing chlorinated lime, chlorine, or aromatic to clean the device and its accessories. Liquid soap containing the humidifying agent or antimicrobials should not be used either. These solutions may harden cleaned materials or reduce their life.
- Do not clean or dry the device and its accessories when the temperature is higher than 80°C(176°F). High temperatures could reduce product life.
- Do not immerse the device in any fluids.

16.1 Cleaning the Mask and Headgear

For details, refer to the cleaning instructions in the user manual for the mask.

16.2 Cleaning the Water Chamber of the Humidifier

For details, refer to the cleaning instructions in the user manual for the humidifier.

16.3 Cleaning the Enclosure

Wipe the surface of the device with a soft, slightly damp cloth.

CAUTION!

- The device can only be used after the enclosure is dry, so that no moisture enters the device.

16.4 Cleaning the Air hose

- (1) Remove the air hose from the device and mask before cleaning.
- (2) Clean the air hose in warm water which contains washing liquid, and then rinse it in clean water thoroughly.
- (3) After cleaning, air-dry the air hose in a cool, well-ventilated area, and avoid direct sunlight. It takes approximately 30 minutes to completely air-dry the air hose. Check whether the air hose is completely dry before re-use.

16.5 Replacing the Air Filter

- (1) Open the air filter cap to remove the air filter.
- (2) Put the new air filter in the filter area, and then place the filter cap back properly.

CAUTIONS!

- To avoid material damage, do not place the spare air filter in direct sunlight, humid environments, or temperatures below the freezing point. The air filter should be replaced every 6 months (It may be replaced more frequently based on actual sanitary conditions).
- Operating the device with a dirty air filter may stop it from working properly and may cause damage to the device.
- Replacing the air filter and filter cap, device must be unplugged.

17. Traveling with the Device

CAUTIONS!

- Empty the water chamber of the humidifier before packing the device for your trip; in order to prevent any remaining water from entering the device.
- Using the device at an incorrect elevation setting could result in airflow pressures higher than the prescribed setting. Always verify the elevation setting when traveling or relocating.
- If the device is used when the atmospheric pressure is out of the stated range (See Section 6), the accuracy of the leakage alert will be affected.

(1) Use the BMC carrying case to carry the device and accessories along with you.

Do not put them in your checked baggage.

(2) This device operates on power supplies of 100-240 V and 50/60 Hz, and is suitable for use in any country in the world. No special adjustment is necessary, but you will need to find out the types of the power sockets in your destination. Bring, if necessary, a power socket adaptor which can be bought in electronics stores.

(3) Remember to bring a spare air filter and the emergency documents (filled and signed by your physician) about this device. If you plan to travel by air, remember to bring the multi-language emergency documents about respiratory therapy, in case that the border and customs officers in your destination country inspect the device. With the emergency documents, you can prove to them that it is a medical device.

(4) Security Stations: For convenience at security stations, there is a note on the bottom of the device stating that it is medical equipment. It may be helpful to bring this manual along with you to help security personnel understand the device.

18. Reordering

Contact your home care provider to order accessories or replacement filters.

The device does not require routine servicing.

WARNINGS!

- If you notice any unexplained changes in the performance of the device, if it is making unusual or harsh sounds, if it has been dropped or mishandled, if the enclosure is broken, or if water has entered the enclosure, discontinue use. Contact your home care provider.
- If the device malfunctions, contact your home care provider immediately. Never attempt to open the enclosure of the device. Repairs and adjustments must be performed by 3B-authorized service personnel only. Unauthorized service could cause injury, invalidate the warranty, or result in costly damage.
- If necessary, contact your local authorized dealer or 3B Medical, Inc. for technical support and documents.

19 Technical Support

Please contact 3B directly if you need the circuit diagram of the device and the list of components for certain purposes such as maintenance or connection to other equipment. 3B will provide the circuit diagram and/or other technical documents in whole or in part according to your needs.

20. Disposal

When the device reaches the end of its service life, dispose of the device and packaging in accordance with local laws and regulations.

21. Troubleshooting

The table below lists common problems you may have with the device and possible solutions to those problems. If none of the corrective actions solve the problem, contact your home care provider.

21.1 Common Problems in Patients and Corresponding Solutions

Problem	Possible Cause	Solution(s)
Dry, cold, runny, and blocked nose; having a cold	The nose reacts to the airflow and cold. Due to fast airflow, the air becomes cold, leading to nasal mucosa irritation and subsequent dryness and swelling.	Increase the humidity setting of the humidifier. Contact your physician, and continue treatment unless the physician suggests the opposite.
Dry mouth and throat	Probably because the patient sleeps with his or her mouth open, and the pressurized air goes out via the mouth, leading to nasal and throat dryness.	Use a chin strap to prevent the mouth from opening during sleep, or use a full-face mask. Contact your physician for details.
Eye irritation	The mask size or model may not be correct, or the mask is not positioned correctly, thereby leading to air leakage.	Narrow the distance between the forehead support of the mask and the forehead. Note that adjusting the mask too tight may leave markings on the patient's face. Add additional filling to the mask so it does not leak. Contact your equipment supplier for an appropriate mask. Add additional filling to the mask if necessary.
	Mask cushion (the soft part of the mask) hardens.	Replace the mask or mask cushion.
Facial reddening	The mask is too tight.	Loosen the headgear.
	The distance between the forehead support of the mask and the forehead is not correct.	Try a different distance. The angle and size of the forehead support differ according to the type of masks.
	Wrong mask size	Contact your equipment supplier for a correct-size mask.

	The patient is allergic to the materials of the mask.	Contact your physician and equipment supplier. Use a latex-free mask. Place a lining between the skin and mask.
Water in mask	When the humidifier is used, the humidified air tends to condense in the cold air hose and mask if the room temperature is low.	Turn the humidity setting down, or raise the room temperature. Place the air hose under the quilt, or use the air hose cover. Hang the air hose loosely, and the lowest part of the air hose should be lower than the patient's head.
Nasal, sinus, or ear pain	Sinus or middle ear inflammation	Contact your physician immediately.
Discomfort due to inability to adapt to the treatment pressure	The patient will feel uncomfortable when the treatment pressure is higher than 13 hPa. However, the treatment pressure is determined according to the patient's conditions, and cannot treat sleep apnea if the treatment pressure is set too low.	It takes a maximum of four weeks to adapt to pressurized air. Relax and breathe through the nose. If the problem still exists, contact your physician.
Obstructive sleep apnea symptoms recur.	Probably because the patient sleeps with his or her mouth open, and the pressurized air goes out via the mouth, leading to blockage in the respiratory tract.	Use a chin strap to prevent the mouth from opening during sleep, or use a full-face mask. Contact your physician for details.
The device is too noisy.	The air hose is not connected properly.	Reconnect the air hose properly.
Air delivered from the device is abnormally hot.	The air inlet of the device may be partially blocked, leading to insufficient airflow into the device.	Replace the air filter (see 16.5 Replacing the Air Filter), and clean the air inlet. Place the device in an area where air flows freely, and make sure the device is at least 20 centimeters away from the wall, curtain, or other things.

20.2 Common Problems in the Device and Corresponding Solutions

Problem	Possible Cause	Solution(s)
The device does not work when it is turned on.	The Auto On/Off feature is enabled	Take a few deep breaths with the mask on, and the device will start automatically.
	Power is not connected properly.	Ensure that the power cord, power adapter, and the device are connected properly.
	There is no voltage.	Check whether a power outage occurs by turning on a light or other means. If you are sure the fuse in the device is broken, contact your equipment supplier for repair.
	Cannot find any cause.	Contact your equipment supplier.
The device is working, but the pressure inside the mask differs from the set treatment pressure.	The air hose is not connected properly.	Reconnect the air hose properly.
	There may be holes in the mask or pressure sensing air hose.	Contact your equipment supplier.
	It is a faulty device.	Contact your equipment supplier.
The device produces very low pressures.	The air inlet of the device may be blocked.	Replace the air filter (see 16.5 Replacing the Air Filter), and clean the air inlet. Make sure the air inlet is unblocked.
	The treatment pressure has been changed accidentally.	Contact your physician.
	When the Ramp feature is enabled, it takes some time for the initial pressure to rise to the treatment pressure. This is normal.	If necessary, disable the Ramp feature, or set the ramp time shorter.
After the device is turned on, the screen displays intermittently, or displays nothing at all.	The operating system of the device needs to be readjusted or restarted.	Unplug the power cord of the device, and re-plug it 20 seconds later.
The device is in	The operating system of	Unplug the power cord of the

standby, and will not start.	the device needs to be readjusted or restarted.	device, and re-plug it 20 seconds later.
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21. EMC Requirements

Guidance and manufacturer's declaration - electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The user of the device should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical home or hospital.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical home or hospital.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or from a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	If the pressure deviates more than is indicated in the device specifications, it may be necessary to position the device further from sources of power frequency magnetic fields. The power frequency magnetic field should be measured in the intended installation location to ensure that it is sufficiently low.
Note: U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 Vrms</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3\sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applied.

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

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

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

Recommended separation distances between portable and mobile RF communications equipment and the device

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

Rated maximum output of transmitter W	150 kHz~80 MHz $d = 1.2\sqrt{P}$	80 MHz~800 MHz $d = 1.2\sqrt{P}$	800 MHz~2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

22. Limited Warranty

3B Medical, Inc. warrants that the Luna E-20 models will be free of all defects in workmanship and materials, and will perform according to specifications, for a period of two (2) years of sale from the sale of the device.

If the product fails to perform in accordance with the product specifications, 3B Medical, Inc. will repair or replace, at its option, the defective material or part. This warranty does not cover damage caused by accident, misuse, abuse, alteration and other defects not related to material or workmanship.

- 3B will issue an RMA (Return Merchandise Authorization) within 24 hours of receipt of written notification of a failed or defective unit. Failed/defective units must be returned within 30 days of the RMA date.
- This warranty coverage is applicable to all 3B/BMC CPAP, Auto-CPAP and Auto Bi-Level devices.
- The warranty policy does not cover any damages caused as a result of alteration, intentional damage, modification, or unauthorized repair of the device.
- 3B reserves the right to amend this policy at any time.

To exercise the rights under this warranty, contact your local authorized dealer or:

3B Medical, Inc.
21301 US Highway 27 N
Lake Wales, FL 33859
T: (863) 226-6285
F: (863) 226-6284

For additional information, please visit our Patient Portal at:
www.3bproducts.com
icodeconnect.com – Web-based cloud for report generation and storage
www.bmc-icode.com – Website for iCode data report retrieval

Issue date: September 22 2014

FDA CDRH DMC

3B™ Medical, Inc.

JAN 05 2015

Received

Alex Lucio, Vice President

alucio@3BProducts.com

863-226-6285 ext. 101

FAX 863-226-6284

December 31, 2014

K141770/S003

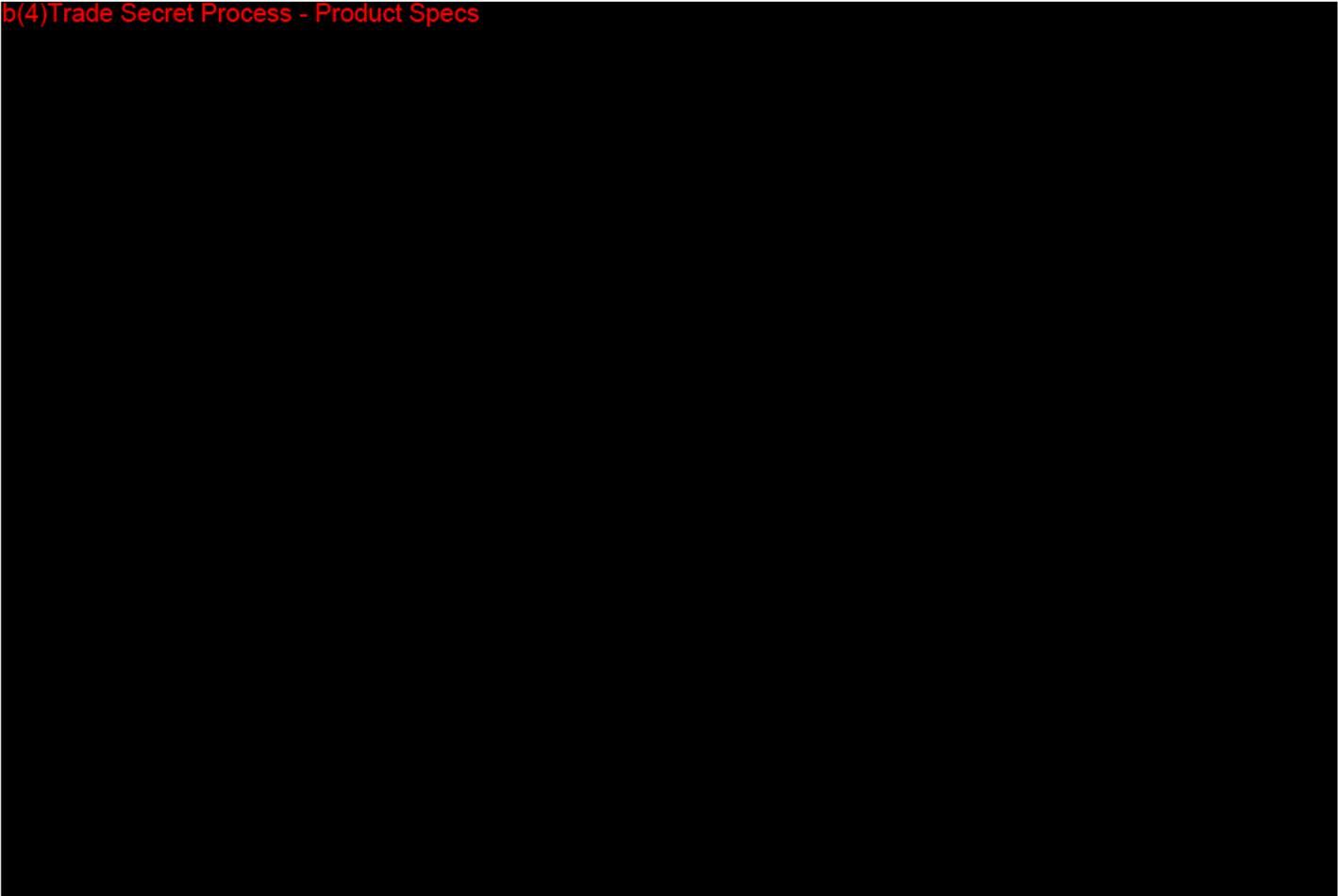


Ms. Sidra Mirza
FDA/CDRH/ODE/DAGRID
Document Control Center WO66, Room 2457
Silver Spring, MD 20993-0002

RE: 510(k) K141770
RESmart GII / Luna CPAP and Auto-CPAP
AI Letter Issued December 5, 2014

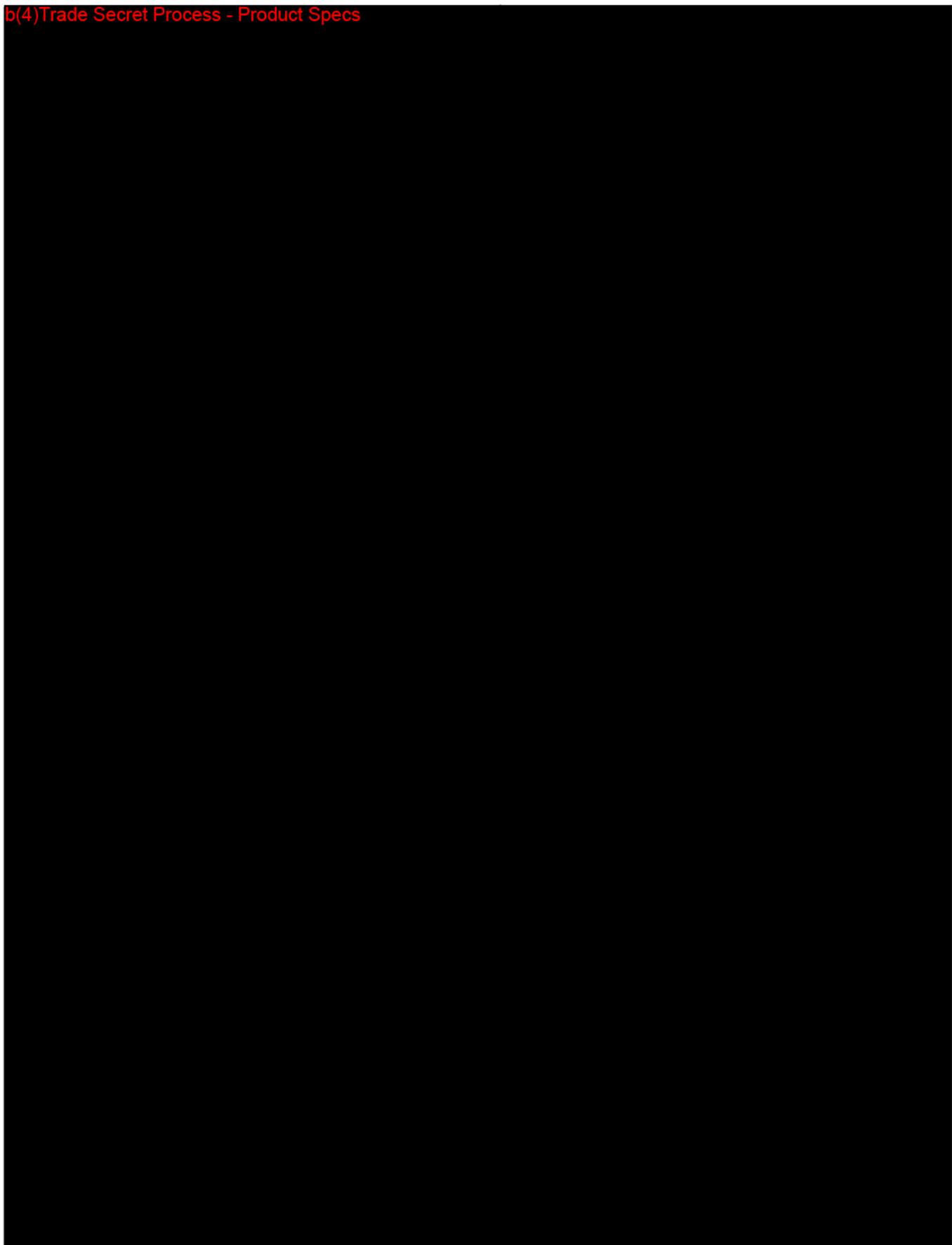
Dear Ms. Mirza,

b(4)Trade Secret Process - Product Specs



42

b(4)Trade Secret Process - Product Specs



b(4)Trade Secret Process - Product Specs

Sincerely,

A handwritten signature in blue ink, consisting of several horizontal strokes and a vertical line, positioned above a horizontal line.

Alex Lucio
Vice President

cc:

b(4)Trade
Secret Process -
Product Specs

AAL/rv

K141770/S004
3B™ Medical, Inc.

Alex Lucio, Vice President
alucio@3BProducts.com

863-226-6285 ext. 101
FAX 863-226-6284

FDA/CDRH/DCC

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March 6, 2015

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Silver Spring, Maryland 20993-0002

RE: 510(k) No. K141770
Response to AI Letter

Dear Sir/Madam:

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Sincerely,

Alex Lucio
Vice President

Cc: Sidra Mirza, BSRC RRT-NPS
File

K141770 | S004

3B™ Medical, Inc.

FDA CDRH DMC Alex Lucio, Vice President

alucio@3BProducts.com

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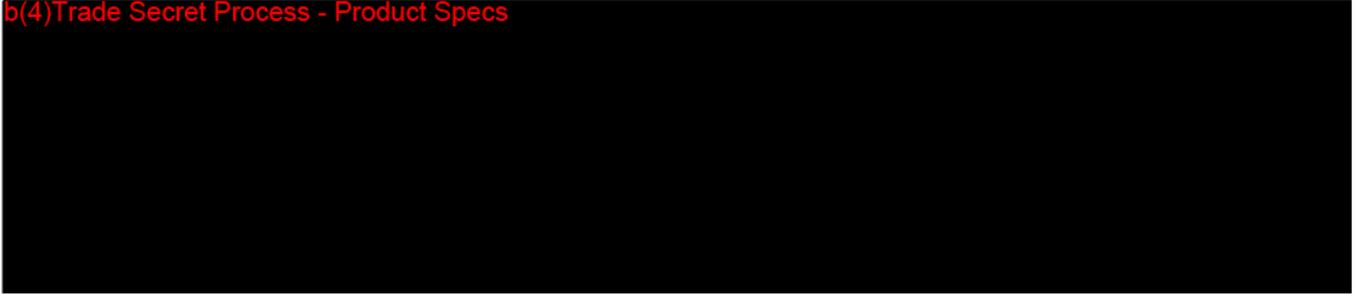
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Silver Spring, Maryland 20993-0002

RE: 510(k) No. K141770
Response to AI Letter

Dear Sir/Madam:

b(4)Trade Secret Process - Product Specs



Sincerely,

A handwritten signature in black ink, appearing to read "Alex Lucio".

Alex Lucio
Vice President

Cc: Sidra Mirza, BSRC RRT-NPS
File

3B™ Medical, Inc.

Alex Lucio, Vice President
alucio@3BProducts.com

863-226-6285 ext. 101
FAX 863-226-6284

March 6, 2015

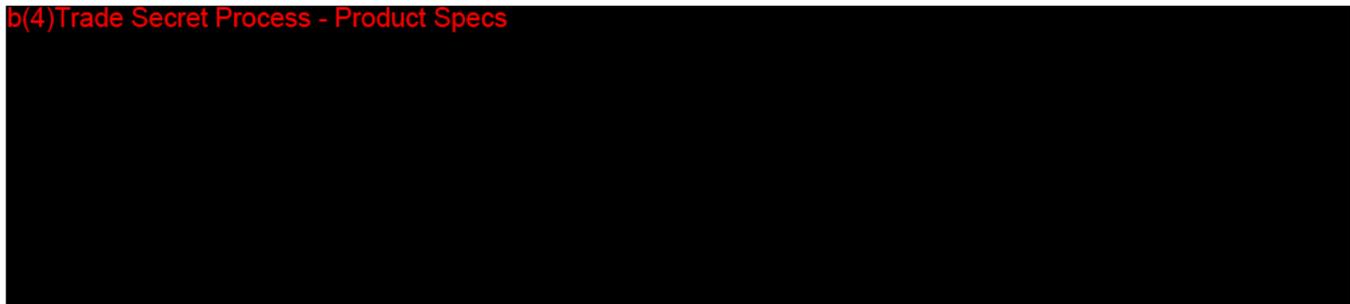


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Silver Spring, Maryland 20993-0002

RE: 510(k) No. K141770
Response to AI Letter

Dear Sir/Madam:

b(4)Trade Secret Process - Product Specs

A large black rectangular redaction box covers the majority of the letter's body text.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Alex Lucio', is written over a horizontal line.

Alex Lucio
Vice President

Cc: Sidra Mirza, BSRC RRT-NPS
File

K141770

3B™ Medical, Inc.

Alex Lucio, Vice President

alucio@3BProducts.com

863-226-6285 ext. 101

FAX 863-226-6284



March 10, 2015

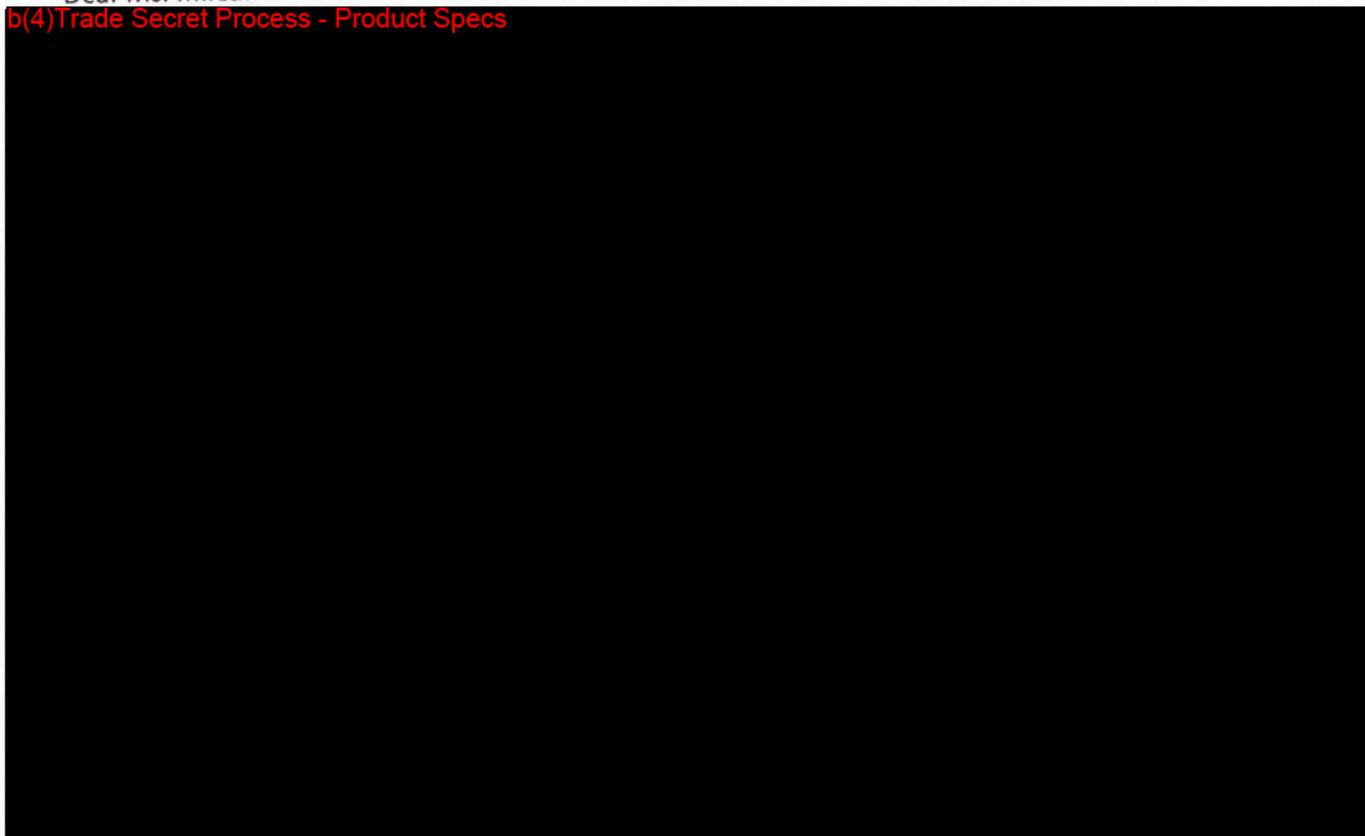
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Att: Sidra Mirza BSRC RRT-NPS

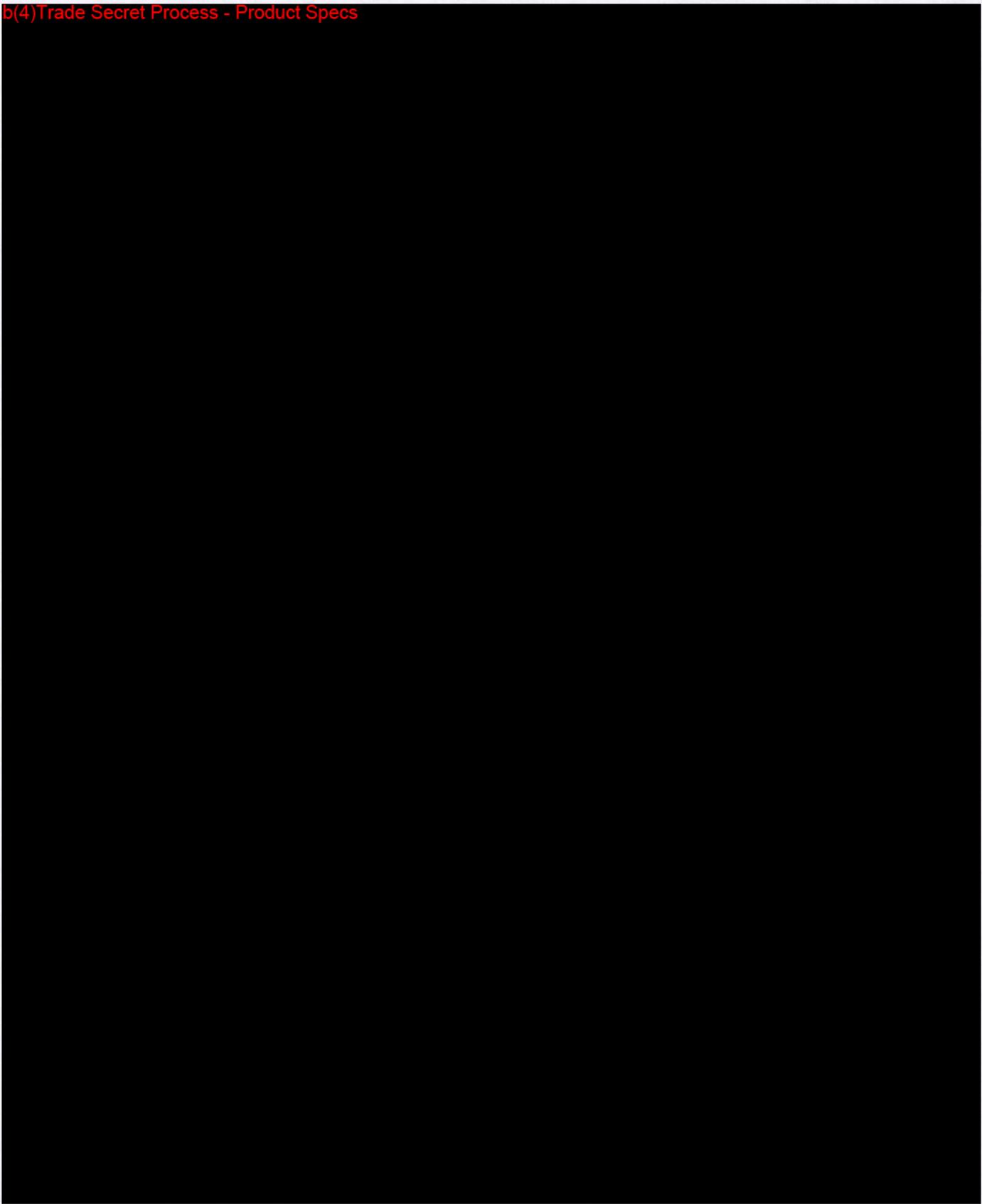
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Response to AI Letter

Dear Ms. Mirza:

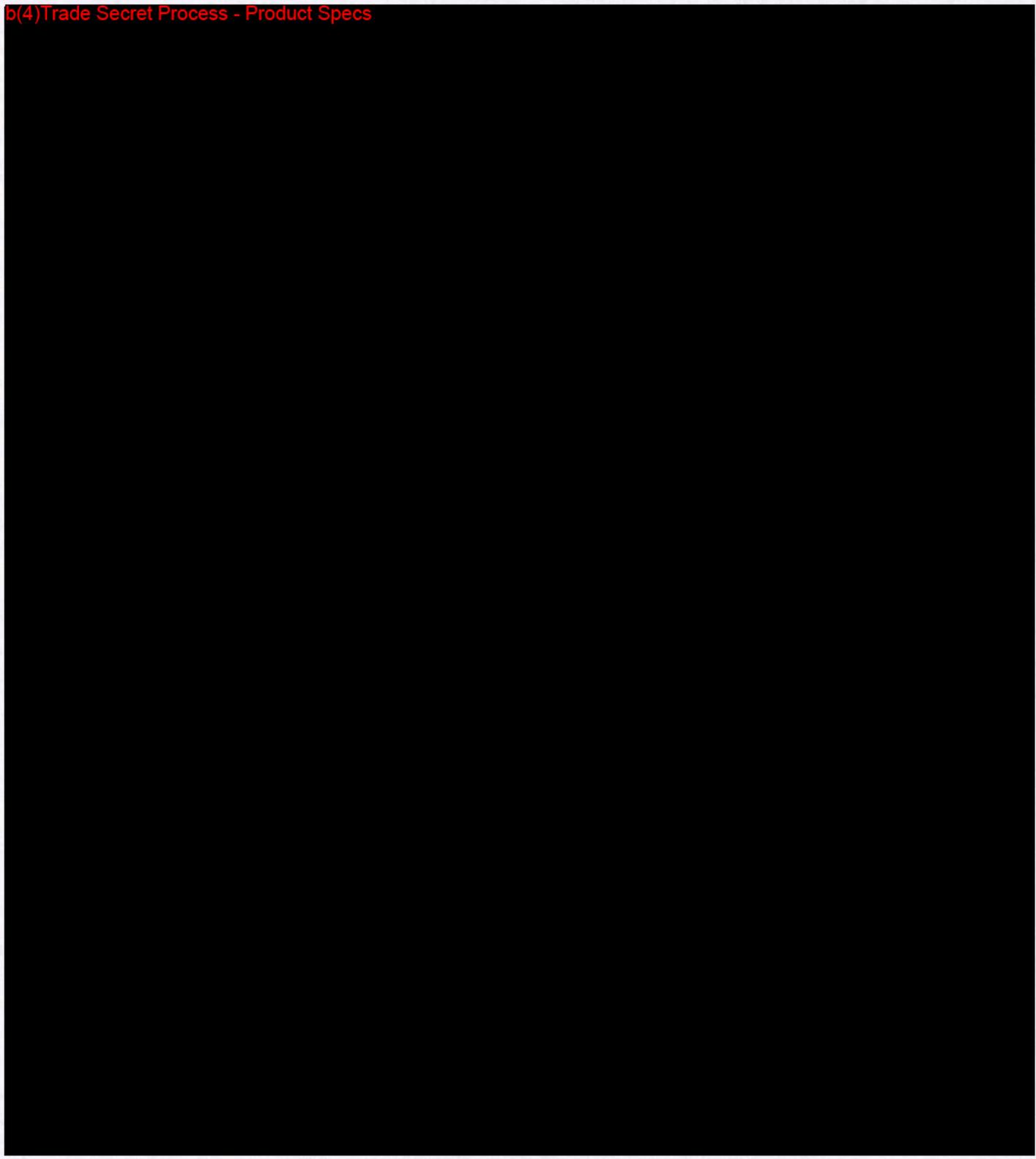
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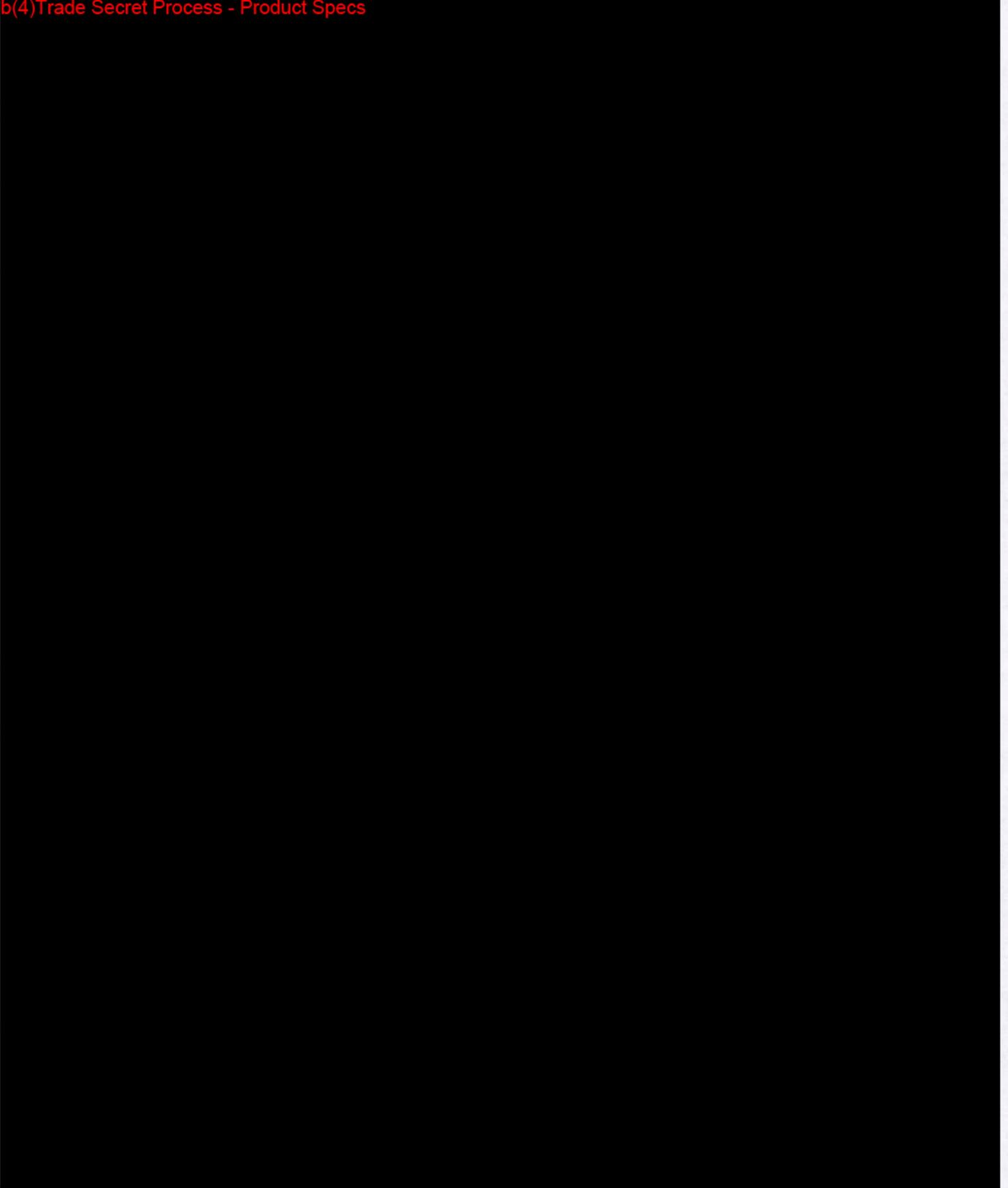
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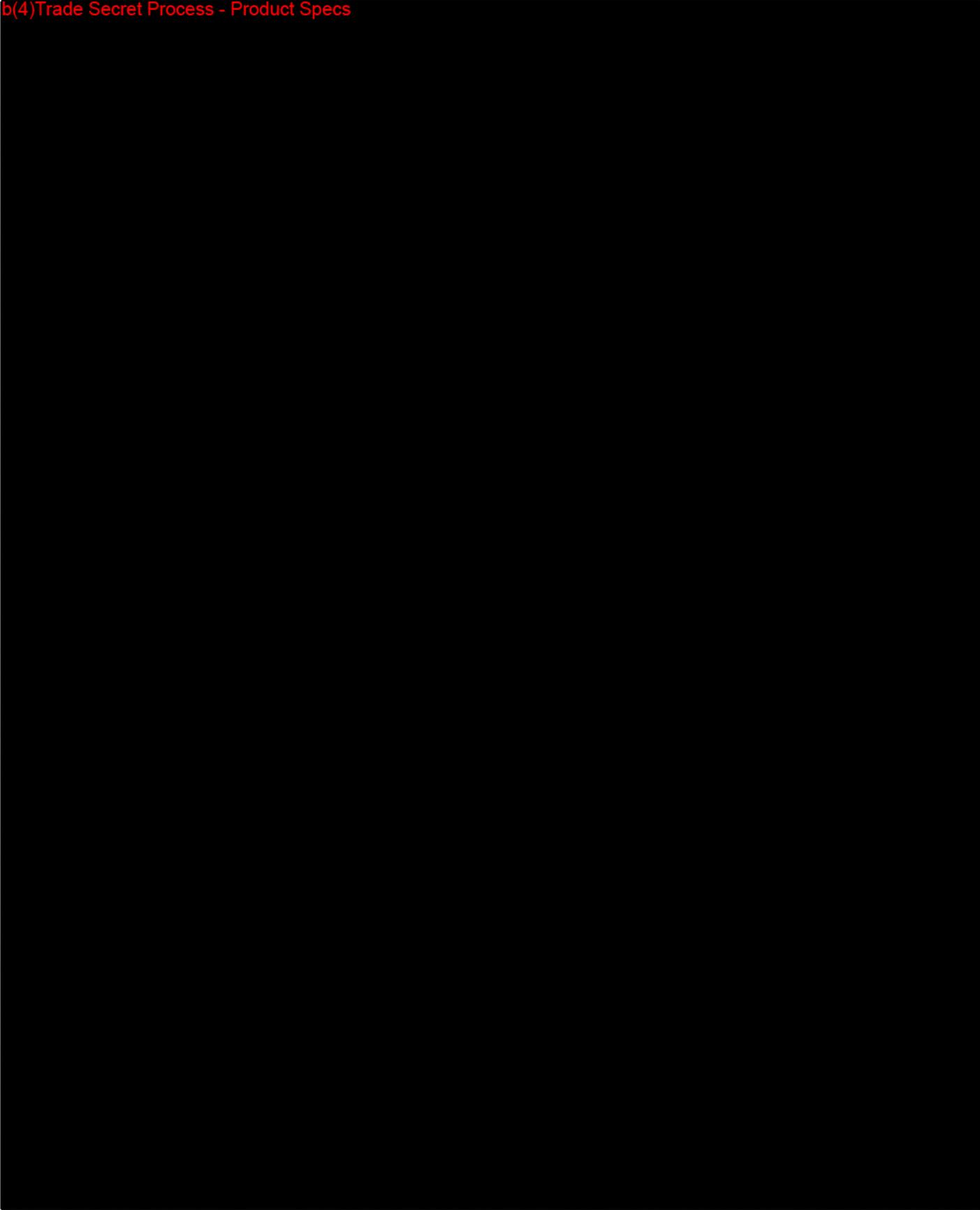
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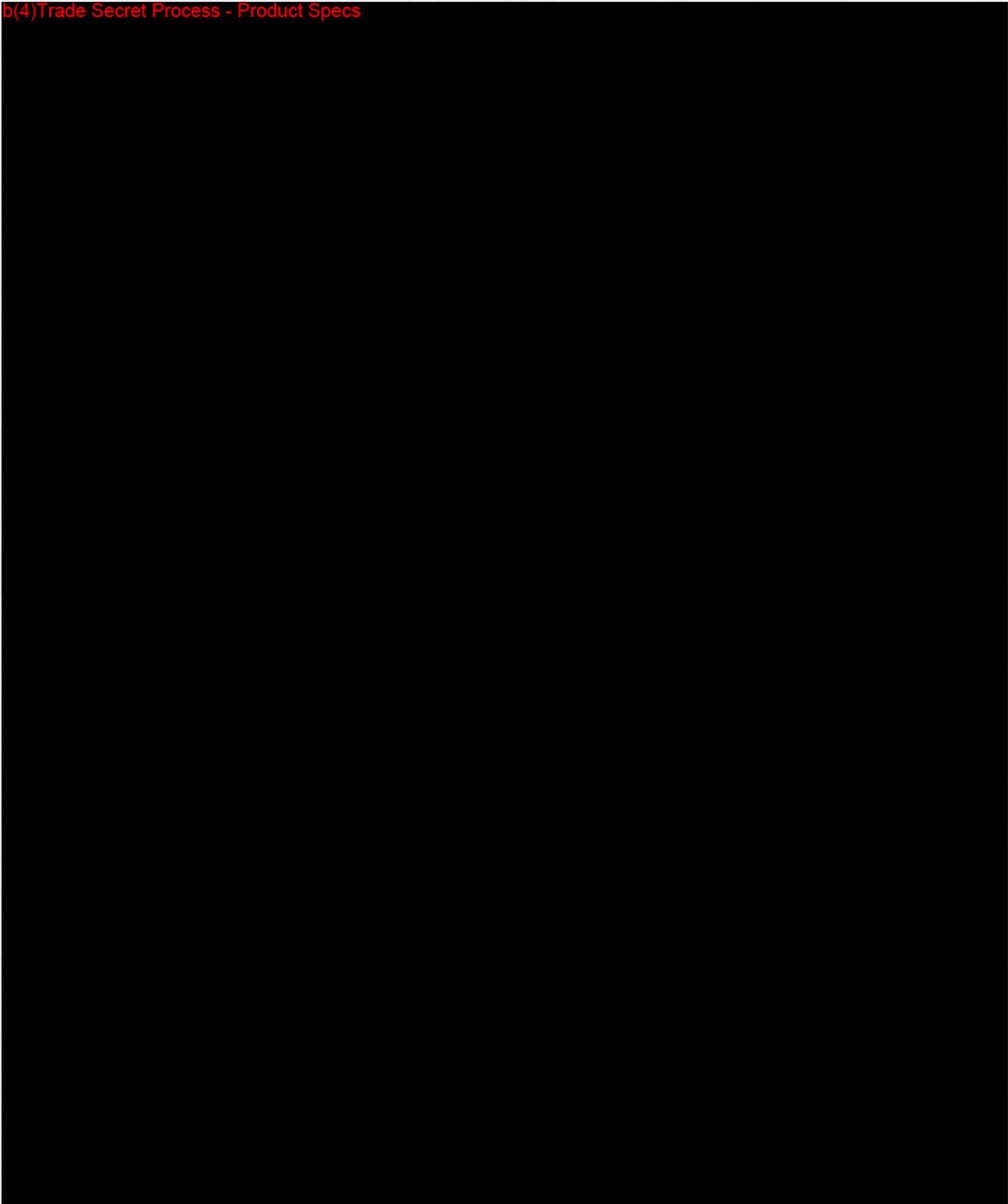
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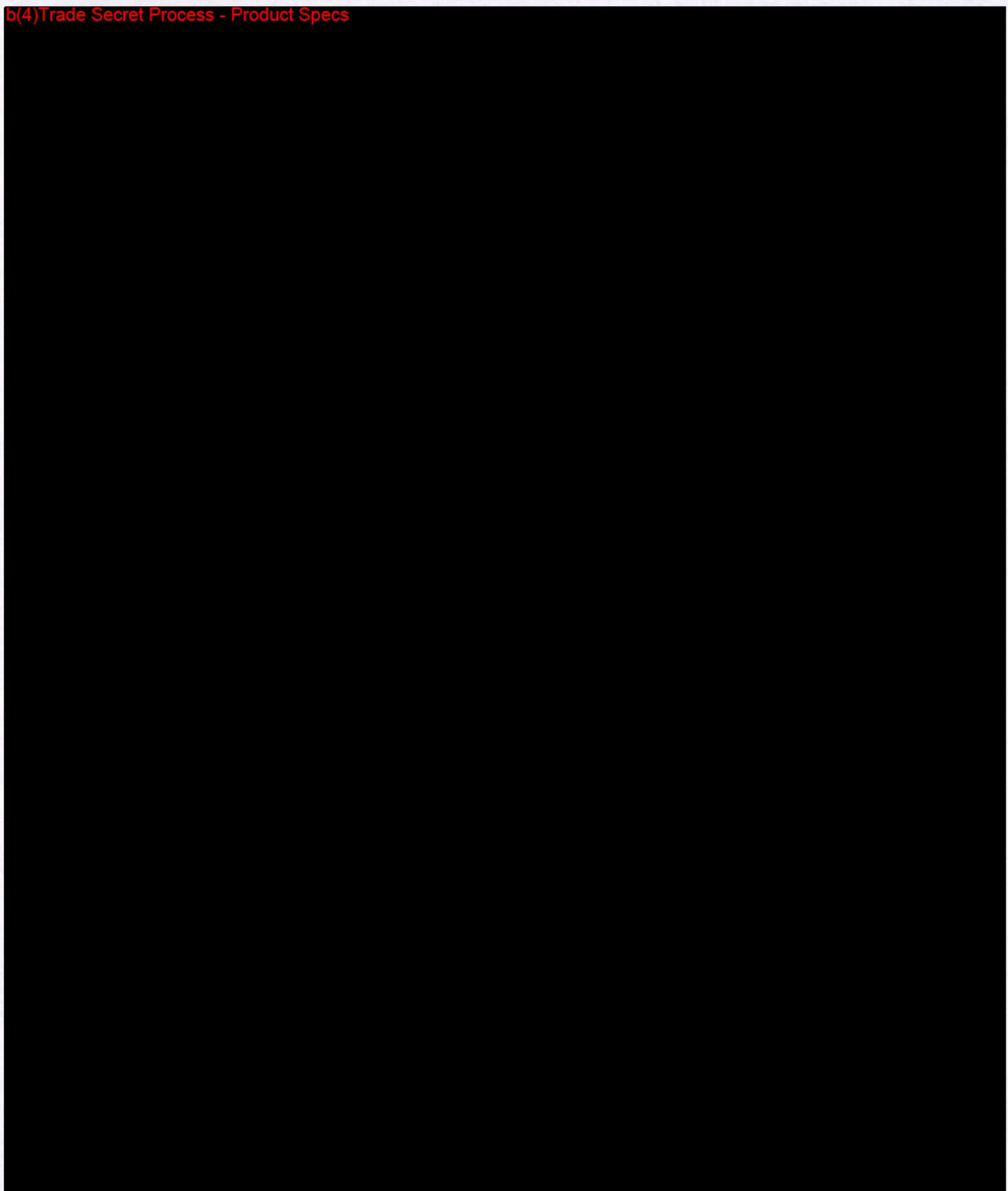
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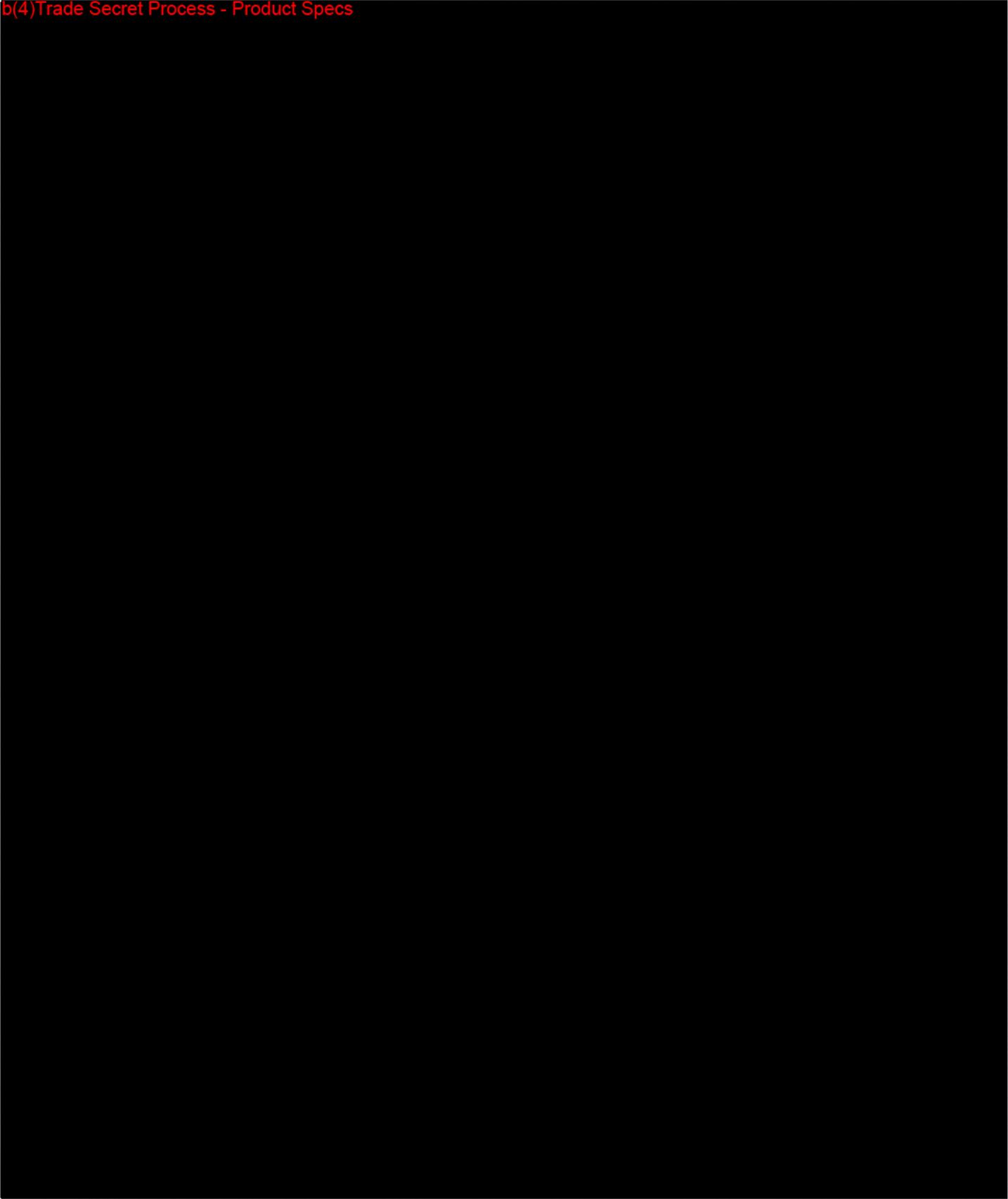
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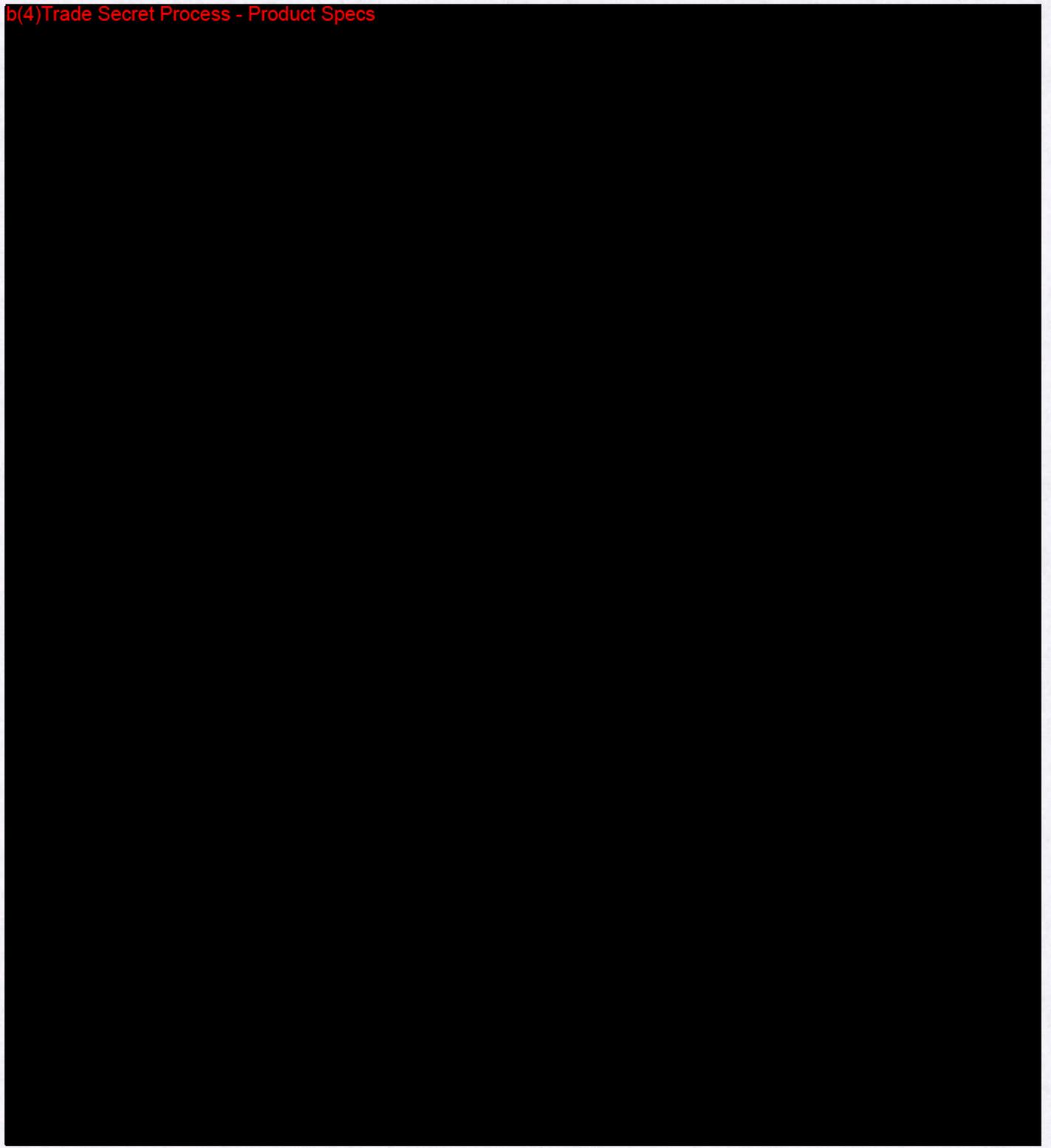
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b(4) Trade Secret Process - Product Specs



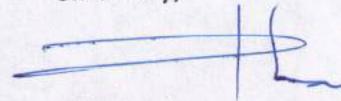
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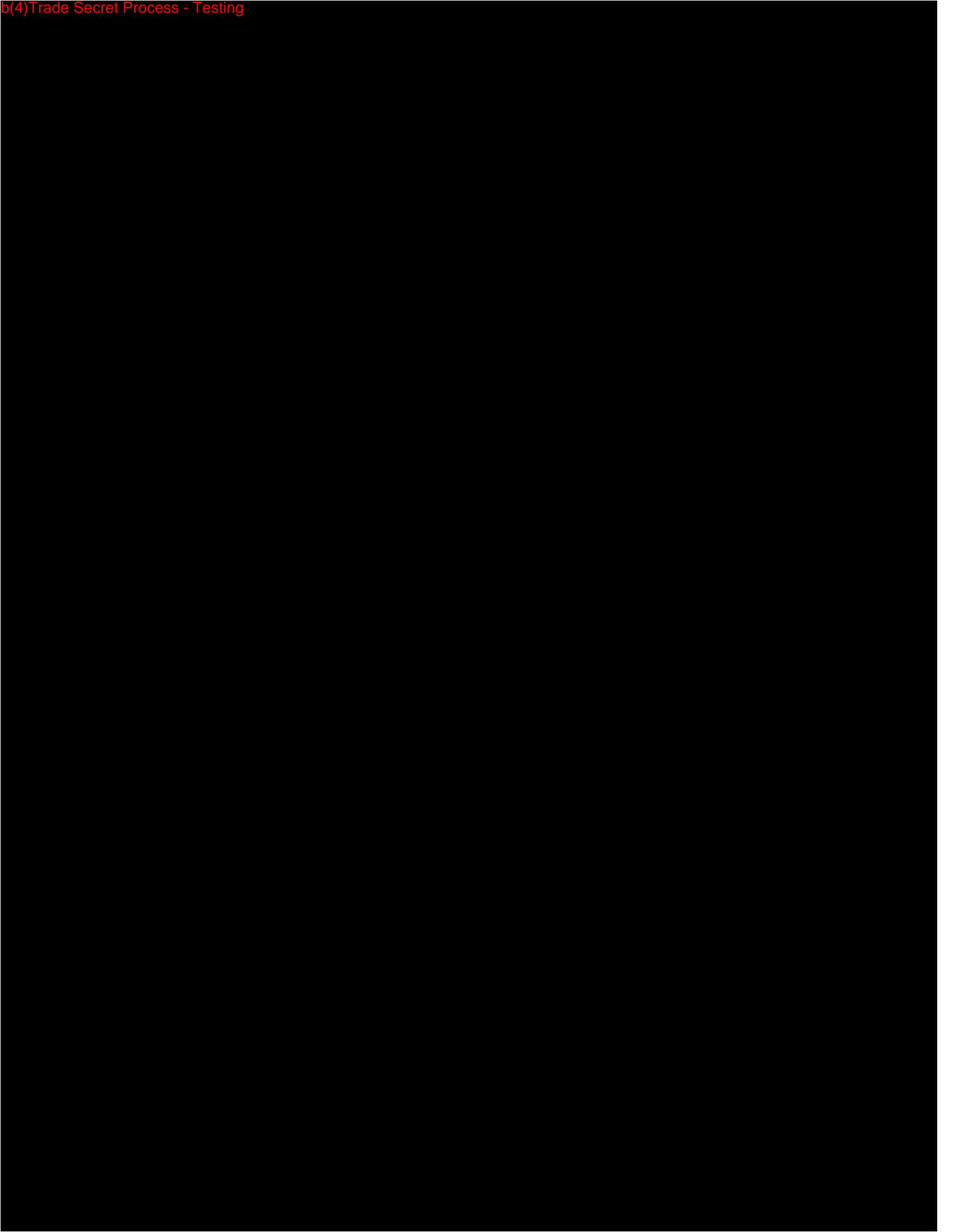
Sincerely,



Alex Lucio

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SUBSTANTIAL EQUIVALENCE COMPARISON CHART

Device: Sleep Apnea Therapy Devices
Luna and RESmart GII

Proprietary Names: CPAP/Auto CPAP System

Manufacturer: BMC Medical Co., Ltd.

No. of Doc.	YF-nP2-5-76		
Version	V1.1		
Drafted by	Pan Fei	Date	
Reviewed by	Houbingying	Date	
Approved by	ZhuangZhi	Date	3/6/15

FEATURES	Proposed Device RESmart GII CPAP and Auto CPAP Systems (also sold as the Luna CPAP and Auto CPAP Systems	Comparison Device RESmart CPAP/APAP (Private labeled as 3B CPAP/APAP)
Therapy Delivered	CPAP, Auto CPAP	CPAP, Auto CPAP
Indications For Use	The 3B and BMC CPAP and Auto CPAP Systems are intended to deliver positive pressure for the treatment of Obstructive Sleep Apnea. The optional integrated humidifier is indicated for the humidification and warming of air from the flow generator. These devices are intended for single patient use by prescription in the home or hospital / institutional environment on adult patients.	The 3B and BMC RESmart CPAP and Auto-CPAP Systems are intended to deliver positive pressure for the treatment of Obstructive Sleep Apnea. The optional integrated humidifier is indicated for the humidification and warming of air from the flow generator device. These devices are intended for single patient use by prescription in the home or hospital/ institutional environment on adult patients.
Patient Population	Adult	Adult
Patient Setting	Home or hospital/ Institutional environment	Home or hospital/ Institutional environment

Dimensions	170 x 196x118 mm, 290 x 196x134 mm (with heated humidifier H60)	220 x 194 x 112 mm (8.66" x 7.64" x 4.41") 313 x 194 x 112 mm (with InH2™ Humidifier)
Weight	1.5kg 2.5kg (with heated humidifier H60)	1.6 kg 2.4 kg (with InH2™ Humidifier))
Operation Temperature	5 to 35° C (41 to 95 F)	5 to 30° C (41 to 86 F)
Storage/ Transport Temperature	-25 to 70° C	-20 to 55° C
Humidity	15% to 93% Non-condensing	≤ 80% Non-condensing
Atmospheric Pressure	76 to 106 kPa	86 to 106 kPa

Standards Compliance	IEC 60601-1 General Requirements for Safety of Medical Electrical Equipment IEC60601-1-11 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment IEC 60601-1-2 Electromagnetic Compatibility ISO 8185:1998 General Requirements for Humidification Systems	IEC 60601-1 General Requirements for Safety of Medical Electrical Equipment IEC 60601-1-2 Electromagnetic Compatibility ISO 8185:1998 General Requirements for Humidification Systems
Mode of Operation	Continuous	Continuous
AC Power Consumption	100-240VAC, 50/60Hz, 2.0A max	100-240VAC, 50/60Hz, 1.0A max
Software	Microprocessor controlled	Microprocessor controlled
System Contents	Air blower, pressure-flow monitoring, pressure controlling, user interface, heated humidifier, power cord, carrying case, user manual.	Air blower, pressure-flow monitoring, pressure controlling, user interface, heated humidifier, power cord, carrying case, user manual.
Type of Protection Against Electric Shock	Class II Equipment	Class II Equipment

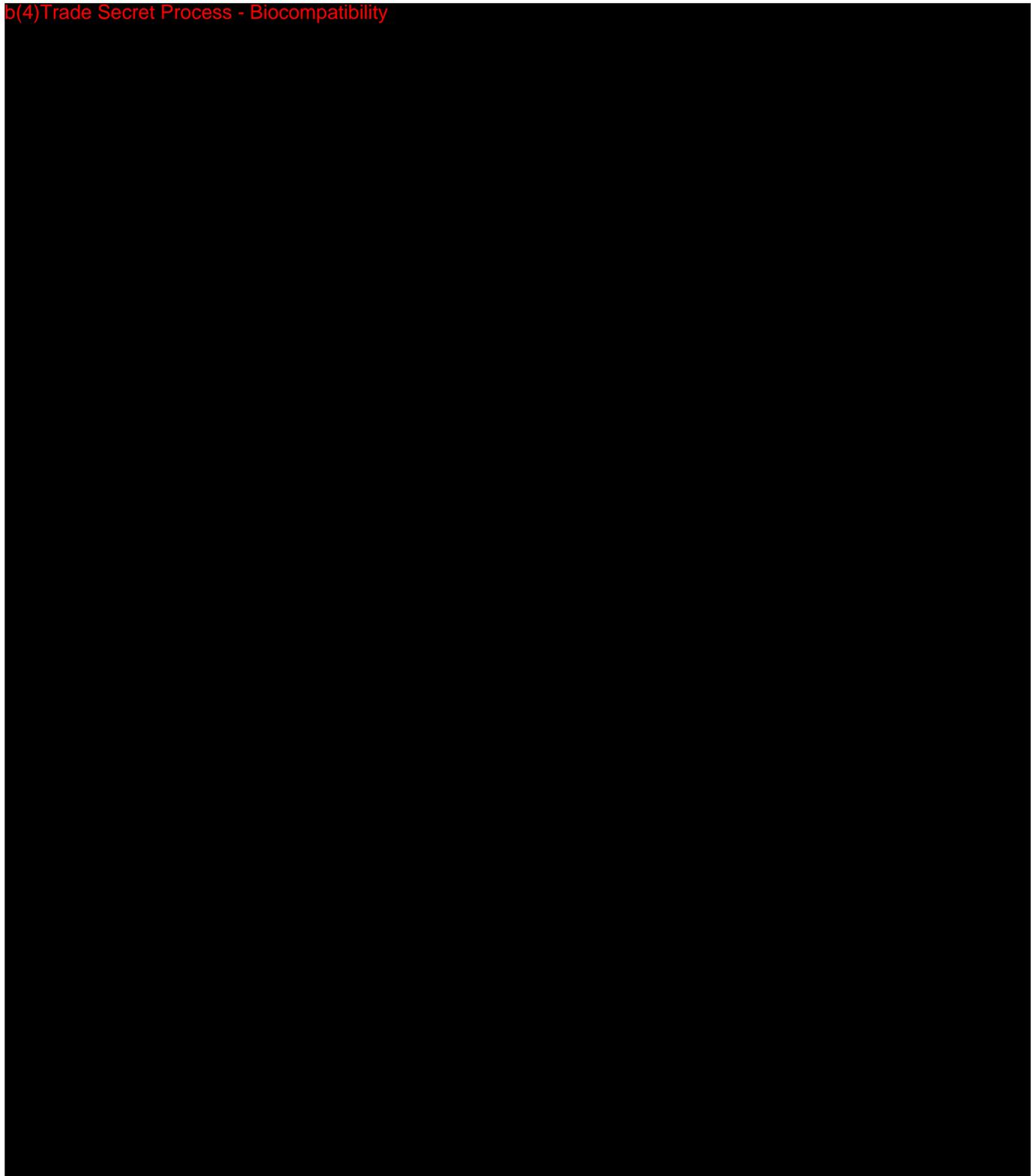
Degree of Protection Against Electric Shock	Type BF Vertical Applied Part	Type BF Vertical Applied Part
Degree of Protection Against Ingress of Water	IP22	IPX1-Drip- Proof, Vertical
Pressure Range	4-20 cmH20 (in 0.5 cmH20 increments)	4-20 cmH20 (in 0.5 cmH2) increments)
Sterilization/ Reuse	Not provided sterile Reusable with cleaning instructions	Not provided sterile Reusable with cleaning instructions
Altitude Compensation	/	Manually Setting Level 0, 1, 2 00 = less than 2,460 ft. (<750 m) 11 = 2,460 to 4,921 ft. (750 m to 1500 m) 22 = 4,924 to 8,202 ft. (1501 m to 2500 m)
Sound Pressure Level	<30 dB, when the device is working at the pressure of 10 cmH20	<30 dB, when the device is working at the pressure of 10 cmH2O.

Housing	ABS	flame retardant Engineering thermoplastic
Pressure Display Accuracy (cmH20)	±(0.5 cmH20+4%)	0.5
Ramp (minutes)	0-60	0-60
Mask off alert	Yes	Yes
Integrated Humidifier	Yes	Yes
Maximum Flow	<p>30LPM</p> <p>Measured in accordance with EN 17510 @ 6.6, 13.2, & 20 cm H2O @ 500 ml with BPM set to 10, 15, & 20 BPM performed at 23 an atmospheric pressure of 101.54 kPascals.</p>	<p>35 LPM</p> <p>Measured in accordance with EN 17510 @ 6.6, 13.2, & 20 cm H2O @ 500 ml with BPM set to 10, 15, & 20 BPM performed at 23 atmospheric pressure of 101.54 kPascals.</p>

static and dynamic pressure accuracies	<p>4 to 20 cmH20(±1 cmH20)</p> <p>Measured in accordance with prEN 17510 @ 6.6, 13.2, & 20 cm H2O @ 500 ml with BPM set to 10, 15, & 20 BPM performed at 23° C (±2° C), 50% RH (±5%), and an atmospheric pressure of 101.5 kPa.</p>	<p>4 to 20 cmH20(±1 cmH20)</p> <p>Measured in accordance with prEN 17510 @ 6.6, 13.2, & 20 cm H2O @ 500 ml with BPM set to 10, 15, & 20 BPM performed at 23° C (±2° C), 50% RH (±5%), and an atmospheric pressure of 101.5 kPa.</p>
alarms and limits	<p>No alarms</p> <p>Patient Disconnect Alert (Air leak Alert)</p> <p>Power-off Alert</p>	<p>No alarms</p> <p>Patient Disconnect Alert (Air leak Alert)</p> <p>Power-off Alert</p>
Humidifier	<p>Yes</p> <p>Water Capacity: 350 ml</p> <p>Heater Settings: 1 to 5 (95 to 167 °F)</p> <p>Pressure Drop with Humidifier < 0.4 cmH20 at 60 LPM flow</p> <p>Humidity Range: ≥10mg/L</p>	<p>Yes</p> <p>Water Capacity:>350 ml</p> <p>Heater Settings: 1 to 5 (104 to 149 °F;</p> <p>Pressure Drop with Humidifier:<0.5 cmH20 at 60 LPM flow;</p> <p>Humidity Range: 10 to 40 mg H₂O/L</p>

BIOCOMPATIBILITY

b(4)Trade Secret Process - Biocompatibility



E-20AJ-H-O

Auto CPAP System

Model: E-20AJ-H-O IP22

AC 100-240V, 50/60Hz, Max 2A

SN E24-----



 **BMC Medical Co., Ltd.**
Made in China

3BTM **3B Medical, Inc.**
21301 US Highway 27 N
Lake Wales, FL 33859
Email: www.3Bproducts.com

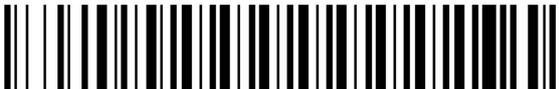
RxOnly

CE 0123

Auto CPAP System

Model: E-20AJ-H-O **RxOnly**

SN E24-----



Gross Weight: --- kg

Dimensions: 355X225X270 mm

Storage Temp: -25~70 °C

Humidity: Up to 93%, non-condensing

 **Manufactured by:**
BMC Medical Co., Ltd.
Made in China

3B Medical, Inc.
21301 US Highway 27 N
Lake Wales, FL 33859
Email: www.3Bproducts.com

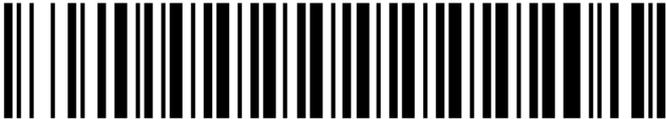
CE 0123

E-20A-H-O

Auto CPAP System

Model: E-20A-H-O
AC 100-240V, 50/60Hz, Max 2A

SN E23-----








 **BMC Medical Co., Ltd.**
Made in China

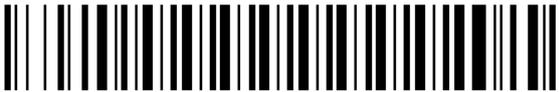
3BTM **3B Medical, Inc.**
21301 US Highway 27 N
Lake Wales, FL 33859
Email: www.3Bproducts.com

RxOnly
CE 0123

Auto CPAP System

Model: E-20A-H-O

SN E23-----



RxOnly
CE 0123

Gross Weight: --- kg

Dimensions: 355X225X270 mm

Storage Temp: -25~70 °C

Humidity: Up to 93%, non-condensing

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3B Medical, Inc.
21301 US Highway 27 N
Lake Wales, FL 33859
Email: www.3Bproducts.com

E-20C-H-O

CPAP System
Model: E-20C-H-O
AC 100-240V, 50/60Hz, Max 2A

IP22

SN E21-----



 **BMC Medical Co., Ltd.**
Made in China

 **3B Medical, Inc.**
21301 US Highway 27 N
Lake Wales, FL 33859
Email: www.3Bproducts.com

RxOnly
CE 0123

CPAP System
Model: E-20C-H-O

SN E21-----



RxOnly
CE 0123

Gross Weight: --- kg

Dimensions: 355X225X270 mm

Storage Temp: -25~70 °C

Humidity: Up to 93%, non-condensing

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Made in China

3B Medical, Inc.
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Lake Wales, FL 33859
Email: www.3Bproducts.com

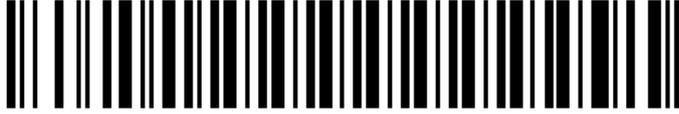
Heated Humidifier

Model: H60

IP22



SN H21-----



BMC Medical Co., Ltd.

Made in China

3B™

3B Medical, Inc.

21301 US Highway 27 N

Lake Wales, FL 33859

Email: www.3Bproducts.com

RxOnly

CE 0123

Heated Humidifier

Model: H60

RxOnly

SN H21-----



CE 0123

Gross Weight: --- kg

Dimensions: 355X225X270 mm

Storage Temp: -25~70 °C

Humidity: Up to 93%, non-condensing



Manufactured by:
BMC Medical Co., Ltd.

Made in China

3B Medical, Inc.

21301 US Highway 27 N

Lake Wales, FL 33859

Email: www.3Bproducts.com

(b) (4)





E-20 System User Manual

E-20C-H-O / E-20A-H-O / E-20AJ-H-O



3BTM
*Solutions in Sleep Therapy*TM
www.3Bproducts.com

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1. Introduction

Thank you for your purchase of the 3B Luna® CPAP / Auto-CPAP System. This User Manual will introduce you to your device. Please read it carefully. If, during use, you experience any difficulties or problems, please contact your homecare provider or physician.

2. Symbols

2.1 Control Buttons

	Ramp Button
	Mute Button
	Knob

2.2 Device Symbols

	Operating Instructions
	Type BF Applied Part (mask)
	Class II (Double Insulated)
	AC Power
	DC Power
IP22	≥ 12.5 mm Diameter, Dripping (15° tilted)
	Hot Surface
	Serial Number of the Product
	Manufacturer
	European CE Declaration of Conformity
	SD Card
	Water Filling Prohibited Here
	Water Inlet
	Directional Indicator for Removing the Water Inlet Cap
	Directional Indicator for Screwing the Water Inlet Cap

3. Warning, Caution and Important Tip

WARNING!

Indicate the possibility of injury to the user or operator.

CAUTION!

Indicate the possibility of damage to the device.

IMPORTANT TIP!

Place emphasis on an operating characteristic.

Warnings, Cautions, and Important Tips appear throughout this manual as they apply.

4. Intended Use

The 3B and BMC CPAP and Auto CPAP Systems are intended to deliver positive pressure for the treatment of Obstructive Sleep Apnea. The optional integrated humidifier is indicated for the humidification and warming of air from the flow generator. These devices are intended for single patient use by prescription in the home or hospital / institutional environment on adult patients.

WARNINGS!

- This device is intended for adult use only.
- This device is not intended for life support.
- The instructions in this manual are not intended to supersede established medical protocols.

CAUTION!

- This device is restricted to sale by or on the order of a physician.
- The device is intended for use by operators trained or experienced in similar equipment.
- The patient is an intended operator.
- Cleaning can be performed by the patient.

IMPORTANT!

- Read and understand the entire user manual before operating this system. If you have any questions concerning the use of this system, contact your home care provider or health care professional.

5. Contraindications

Studies have shown that the following pre-existing conditions may contraindicate the use of positive airway pressure therapy for some patients:

Absolute Contraindications: pneumothorax, mediastinal emphysema; cerebrospinal fluid leak, traumatic brain injury, or pneumocephalus; shock caused by a variety of conditions before treatment; active epistaxis; upper gastrointestinal bleeding before treatment; coma or impaired consciousness making the use of mask during therapy impossible; giant vocal fold polyp, etc.

Relative Contraindications: severe coronary heart disease complicated with left ventricular failure, acute otitis media, excessive respiratory secretions and weak cough, weak spontaneous breathing, nasal or oral tracheal intubation and tracheotomy, severe nasal congestion caused by a variety of conditions, lung bullae, and allergies to breathing masks, etc.

The following side effects may occur during treatment:

- Dryness of the mouth, nose and throat
- Abdominal bloating
- Ear or sinus discomfort
- Eye irritation
- Skin irritation due to the use of a mask
- Chest discomfort

IMPORTANT!

- An irregular sleep schedule, alcohol consumption, obesity, sleeping pills, or sedatives may aggravate your symptoms.
- Please use the mask which meets ISO17510-2:2009.

CAUTION!

- Contact your health care professional if symptoms of sleep apnea recur. Contact your health care professional if you have any questions concerning your therapy.

6. Specifications

Device Size

Dimensions: 170 mm × 196 mm × 118 mm, or 290 mm × 196 mm × 134 mm (with the humidifier)

Weight: 1.5 kg, or 2.5 kg (with the humidifier)

Product Use, Transport and Storage

	Operation	Transport and Storage
Temperature:	5°C to 35°C (41°F to 95°F)	-25°C to 70°C (-13°F to 158°F)
Humidity:	15% to 93% Non-condensing	15% to 93% Non-condensing
Atmospheric Pressure:	760 ~ 1060 hPa	760 ~ 1060 hPa

Mode of Operation

Continuous

Work Mode

For E-20C system: CPAP

For E-20A system: CPAP, Auto

SD Card

With a capacity ≥ 2 G, the SD card can record patient data and fault information. Furthermore, the language pack stored on the SD card enables you to change the language of the device.

AC Power Consumption

100 ~ 240 V AC, 50 / 60 Hz, 2.0 A max

Type of Protection Against Electric Shock

Class II Equipment

Degree of Protection Against Electric Shock

Type BF Applied Part

Degree of Protection Against Ingress of Water

IP22

Pressure Range

4 to 20 hPa (in 0.5 hPa increments), ≤ 30 hPa under single fault conditions.

Pressure Display Accuracy

$\pm(0.5 \text{ hPa} + 4\%)$

Pressure Stability

4 to 20 hPa (± 1 hPa)

Ramp

The ramp time ranges from 0 to 60 minutes

Sound Pressure Level

< 30 dB, when the device is working at the pressure of 10 hPa.

Sound Power Level

< 38 dB, when the device is working at the pressure of 10 hPa.

Maximum Flow

Test Pressure (hPa)	4	9	15	20
Average Flow at the Patient Connection Port (L/min)	80	92	91	96

Air Hose

Length: 6 ft. (1.83 m)

The Form and the Dimensions of the Patient Connection Port

The 22 mm conical air outlet complies with ISO 5356-1

7. Available Therapies

The device delivers the following therapies:

CPAP – Delivers Continuous Positive Airway Pressure; CPAP maintains a constant level of pressure throughout the breathing cycle. If your health care professional has prescribed ramp for you, you can press **the Ramp Button**  to reduce the pressure and then gradually increase the pressure to the therapeutic pressure setting so that you can fall asleep more comfortably.

Auto – Delivers CPAP therapy and provides an air pressure no less than the prescribed one based on the patient's needs.

8. Glossary

Apnea

A condition marked by the cessation of spontaneous breathing.

Auto-CPAP

Adjust CPAP pressure automatically to improve patient comfort based on monitoring of apnea and snoring events.

Auto Off

When this feature is enabled, the device automatically discontinues therapy whenever the mask is removed.

Auto On

When this feature is enabled, the device automatically initiates therapy when you breathe into the mask.

CPAP

Continuous Positive Airway Pressure.

iCode

A feature that is intended to give access to compliance and therapy management information. The "iCode" consists of six separate codes displayed in the Patient Menu. iCode I displays sequences of characters, and iCode II displays two-dimensional codes.

LPM

Liters Per Minute.

OSA

Obstructive Sleep Apnea.

Patient Menu

The display mode in which you can change patient-adjustable device settings, such as the starting pressure for the Ramp feature.

Ramp

A feature that may increase patient comfort when therapy is started. It can reduce pressure and then gradually increase the pressure to the prescription setting so the patient can fall asleep more comfortably.

Reslex

A therapy feature that is enabled by your home care provider to provide pressure relief during exhalation.

Standby State

The state of the device when power is applied but the airflow is turned off.

9. Model

Model	Product Description			
	Product Contents	Work Mode	Size (mm)	Weight (kg)
E-20C-H-O	Main device (2.4-inch LCD), Heated Humidifier (H60)	CPAP	290 (W) × 196 (D) × 134 (H)	2.5
E-20A-H-O	Main device (3.5-inch LCD), Heated Humidifier (H60)	CPAP Auto	290 (W) × 196 (D) × 134 (H)	2.5
E-20AJ-H-O	Main device (2.4-inch LCD), Heated Humidifier (H60)		290 (W) × 196 (D) × 134 (H)	2.5

10. Package Contents

After unpacking the system, make sure you have everything shown here:

No.	Articles	Qty.	Notes
1	Main Device	1	
2	Heated Humidifier	1	Optional
3	Shield	1	
4	Air Filter	2	
5	Power Adapter	1	
6	Power Cord	1	
7	SD Card	1	Optional
8	Carrying Case	1	
9	User Manual	1	
10	Quick Operation Manual	1	

All parts and accessories are not made with natural rubber latex.

The expected service life of the main device is 5 years.

IMPORTANT!

- If any of the above parts are missing, contact your home care provider.
- Contact your home care provider for additional information on the available accessories of this device. When using optional accessories, always follow the instructions enclosed with the accessories.

WARNING!

- The use of inappropriate masks and accessories may affect the performance of the device and impair the effectiveness of therapy.

11. System Features

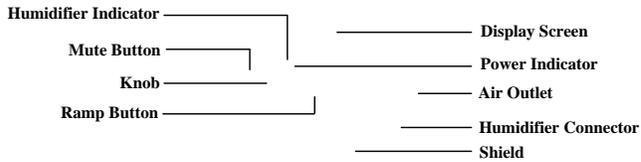


Fig. 11-1

Name	Function
Humidifier Indicator	Indicate the humidity level. There are five levels in total. The number of blue indicator lights that light up is directly proportional to the humidity level. If none of the indicator lights light up, it means the humidifier is turned off
Mute Button	Press this button to mute the alert. However, if the problem causing the alert is not solved, the alert will sound again two minutes later
Knob	Start treatment and adjust device settings
Ramp Button	Enable the Ramp feature
Display Screen	Display menus for operation, messages, monitoring data, etc.
Power Indicator	Indicate the power supply status with the green indicator light
Air Outlet	Deliver pressurized air; connected to the air hose or the air inlet of the humidifier
Humidifier Connector	Provide power to the humidifier which is connected to the main device
Shield	Connect the humidifier to the main device after this shield is removed

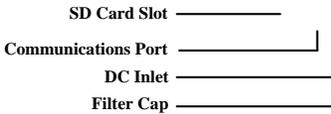


Fig. 11-2

Name	Function
SD Card Slot	Insert the SD card into this slot
Communications Port	Connected to external equipment
DC Inlet	An inlet for the DC power supply
Filter Cap	Place the cap on the air filter, which is used to filter dust and pollen in the air entering the device

12. First Time Setup

12.1 Placing the Device

Place the device on a firm, flat surface.

WARNINGS!

- If the device has been dropped or mishandled, if the enclosure is broken, or if water has entered the enclosure, disconnect the power cord and discontinue use. Contact your home care provider immediately.
- If the room temperature is warmer than 95°F (35°C), the airflow produced by the device may exceed 109.4°F (43°C). The room temperature must be kept below 95°F (35°C) while the patient uses the device.

CAUTIONS!

- If the device has been exposed to either very hot or very cold temperatures, allow it to adjust to room temperature (approximately 2 hours) before beginning setup.
- Make sure the device is away from any heating or cooling equipment (e.g., forced air vents, radiators, air conditioners).
- The device is not suitable for use in high humidity environments. Make sure that no water enters the device.
- Make sure that bedding, curtains, or other objects (such as pests) are not blocking or entering the filter or vents of the device.
- Keep pets or children away from the device.
- To avoid explosion, this device must not be used in the presence of flammable gases (e.g. anesthetics).

- Tobacco smoke may cause tar build-up within the device, leading to the malfunctioning of the device.
- Air must flow freely around the device for it to work properly.

12.2 Installing the Air Filter and Filter Cap

(1) Attach the air filter to the filter cap, as shown in Fig. 12-1.

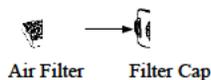


Fig. 12-1

(2) Install the filter cap containing the air filter to the main device, as shown in Fig. 12-2.

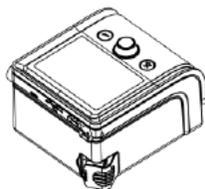


Fig. 12-2

CAUTION!

- The air filter must be in place when the device is operating.
- Installing the air filter and filter cap, device must be unplugged.

12.3 Connecting to Power

- (1) Insert the plug of the power adapter into the DC Inlet on the back of the device;
- (2) Connect the power cord to the power adapter;
- (3) Plug the other end of the power cord into the power outlet.

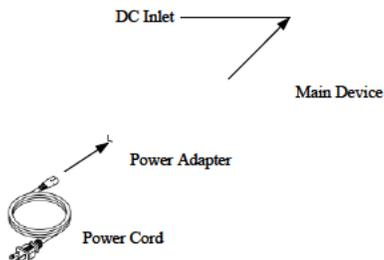


Fig. 12-3

WARNINGS!

- The device is powered on for use when the power cord and power adapter is connected. The **Knob**  turns the blower On / Off.
- Use of the device at an AC voltage beyond the stated range (see Section 6 “AC Power Consumption”) may damage the device or cause device failure.

CAUTION!

- Inspect the power cord often for any signs of damage. Replace a damaged cord immediately.

IMPORTANT!

- After interruption and restoration of the power supply, the device will restore its pre-interruption working status automatically.
- To remove AC power, disconnect the power cord from the power outlet.

12.4 Assembling the Air hose and Mask

(1) Connect one end of the air hose to the air outlet of the main device, as shown in Fig. 12-4. If the main device is used with a humidifier, connect one end of the air hose to the air outlet of the humidifier, as shown in Fig. 12-5.

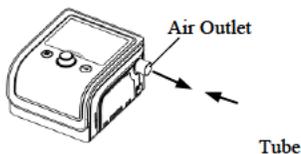


Fig. 12-4

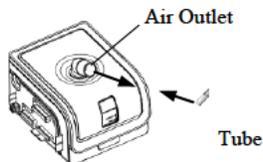


Fig. 12-5

(2) Connect the other end of the air hose to the mask according to the user manual for the mask. Wear the mask.

WARNINGS!

- If you are using a mask with a built-in exhalation port, connect the mask's connector to the air hose.
- If you are using a mask with a separate exhalation port, connect the air hose to the exhalation port. Position the exhalation port so that the vented air is blowing away from your face. Connect the mask's connector to the exhalation port.

- If you are using a full-face mask (a mask covering both your mouth and nose), the mask must be equipped with a safety (entrainment) valve.
- In order to minimize the risk of CO₂ rebreathing, the patient should observe the following instructions:
 - Do not wear the mask for more than a few minutes while the device is not operating.
 - Use only masks with vent holes. Do not block or try to seal the vent holes in the exhalation port.

12.5 Using Oxygen with the Device

Oxygen may be added at the mask connection. Please observe the instructions listed below when using oxygen with the device.

WARNINGS!

- Connect the oxygen air hose to the oxygen inlet of the mask.
- The oxygen supply must comply with the local regulations for medical oxygen.
- Turn on the device before turning on the oxygen. Turn off the oxygen before turning off the device. Explanation of Warning: When the device is turned off, but the oxygen flow still exists, oxygen may accumulate within the device's enclosure and pose a fire hazard. Turning off the oxygen before turning off the device will prevent oxygen accumulation in the device and reduce the risk of fire. This warning applies to most CPAP devices.
- Oxygen supports combustion. Keep the device and the oxygen container away from heat, open flames, any oily substances, or other sources of ignition. DO NOT smoke in the area near E-20C / E-20A or the oxygen container.
- Sources of oxygen should be located more than 1 m from the device.

12.6 Inserting the SD Card

Insert the SD card into the SD Card Slot, as shown in Fig. 12-6.

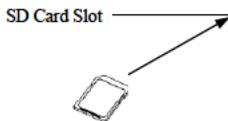


Fig. 12-6

If the SD card is inserted correctly, a symbol indicating correct insertion will appear in the Main Interface on the screen of the device, as shown in Fig. 12-7.

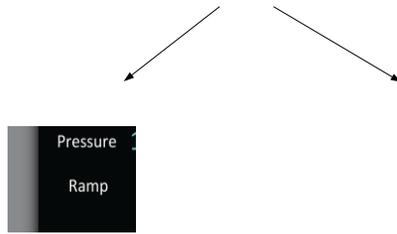


Fig. 12-7

If the SD card is inserted incorrectly or not inserted, a symbol indicating incorrect insertion or no SD card present will appear in the Main Interface on the screen of the device, as shown in Fig. 12-8.

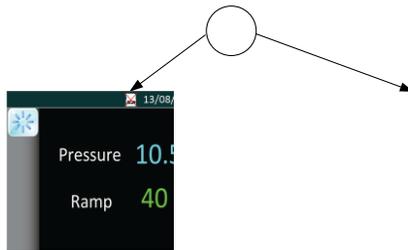


Fig. 12-8

CAUTION!

- To avoid data loss or any damage to the SD card, the SD card can only be removed after the main device stops delivering air.

12.7 Using the H60 Heated Humidifier

The H60 Heated Humidifier is available from your home care provider. The humidifier may reduce nasal dryness and irritation by adding moisture (and heat if applicable) to the airflow. For detailed information about the heated humidifier, please see the user manual for the heated humidifier.

12.8 Starting Treatment

Connect the device to a power outlet, press **the Knob** , and the device will start delivering air.

WARNINGS!

- Be sure to follow your physician's instructions on adjusting the settings! To order any accessories not included with this device, contact your equipment supplier.
- DO NOT connect any ancillary equipment to this device unless recommended by your homecare provider or your physician. If you suffer from chest discomfort,

shortness of breath, stomach bloating, or severe headache when using the device, contact your physician or qualified medical personnel immediately.

13. Routine Use

13.1 Connecting the Air hose

Connect the power cord, power adapter, and air hose properly according to the instructions in the First Time Setup (Chapter 12). Connect the mask and headgear according to the user manual for the mask.

CAUTION!

- Before each use, examine the air hose for any damage or debris. If necessary, clean the air hose to remove the debris. Replace any damaged air hose. Make sure that the mask does not leak.

13.2 Adjusting the Air hose

Lie down on your bed, and adjust the air hose so it is free to move if you turn during sleep. Adjust the mask and headgear until you have a comfortable fit and until there are no airflow leaks into your eyes.

13.3 Turning on the Airflow

Press **the Knob**  to turn on the airflow. The screen will display treatment pressure and other information.

13.4 Heating the Water in the Humidifier

Pay attention to the humidifier indicator lights when using the device with a humidifier. The indicator lights indicate the On / Off state of the humidifier. It is off when all indicator lights go out.

CAUTION!

- Observe the water level of the water chamber before using the humidifier. Make sure there is sufficient water in the water chamber, and avoid heating the humidifier with an empty water chamber.

13.5 Using the Ramp Button

Every time **the Ramp Button**  is pressed, the pressure will drop to the initial pressure, and then gradually rise to the prescribed treatment pressure according to the preset ramp time, so as to make the patient fall asleep easily. The screen displays a real-time countdown of the remaining ramp time in minutes.

CAUTIONS!

- You can press **the Ramp Button**  as often as you wish during sleep.

- The ramp feature is not prescribed for all users.

13.6 Turning the Device Off

Take off the mask and headgear, press and hold **the Knob**  for two seconds, and the device will stop delivering air. Disconnect the power cord from the power outlet to power off the device.

CAUTIONS!

- Do not position the device so that it is difficult to operate the disconnection device.
- To isolate the device from the supply mains, disconnect the plug.

14. Navigating the Patient Menu

14.1 Steps to Navigating the Patient Menu

14.1.1 Accessing the Main Interface

Connect the power cord and power adapter properly. The screen displays the Main Interface shown in Fig. 14-1 (applies to E-20A-H-O), or the Main Interface shown in Fig. 14-2 (applies to E-20C-H-O and E-20AJ-H-O).

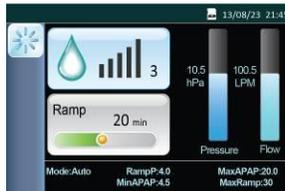


Fig. 14-1



Fig. 14-2

14.1.2 Bringing up the Initial Setup Interface

From the Main Interface shown in Fig. 14-1 or Fig. 14-2, or when the device delivers air, press and hold **the Ramp Button**  for three seconds. The screen displays the Initial Setup Interface of the Patient Menu, as shown in Fig. 14-3.



Fig. 14-3

The first icon  on the left side of the screen indicates the Main Interface, and the second icon  indicates the Initial Setup Interface. As you turn **the Knob** , the cursor switches between the two icons, and the interface displayed on the screen changes accordingly.

14.1.3 Accessing the Setup Interface

When the cursor is on the icon , the screen displays the Setup Interface. Access the Setup Interface by pressing **the Knob** . The first option on the Setup Interface is then displayed in blue, as shown in Fig. 14-4.



Fig. 14-4

14.1.4 Selecting Options

As you turn **the Knob**  clockwise, the cursor moves downwards from one option to another. As you turn it counterclockwise, the cursor moves upwards. When the cursor is on a certain option, press **the Knob** , and the option is then displayed in yellow, meaning that the option can now be adjusted, as shown by the **Humidifier** option in Fig. 14-5.



Fig. 14-5

14.1.5 Adjusting Options

Adjust the option by turning **the Knob** . As shown in Fig. 14-5, the **Humidifier** option is selected. As you turn **the Knob**  clockwise, the numbering increases, indicating a higher humidity level. As you turn **the Knob**  counterclockwise, the numbering

decreases, indicating a lower humidity level. At this moment, the **Humidifier** option is still displayed in yellow, as shown in Fig. 14-6.



Fig. 14-6

14.1.6 Confirming Adjustments

Confirm your adjustment to an option by pressing **the Knob** . The option is then displayed in blue, as shown in Fig. 14-7.



Fig. 14-7

14.1.7 Turning Pages

When the cursor is on **Mask Type**, the last option shown in Fig. 14-7, the remaining options will appear on a new page if you continue to turn **the Knob**  clockwise, as shown in Fig. 14-8.

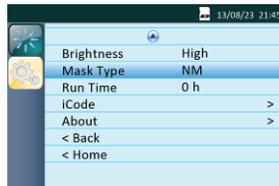


Fig. 14-8

Note:  are page turning symbols.

14.1.8 Exiting the Patient Menu

(1) Returning to the Initial Setup Interface

Move the cursor to the **Back** option by turning **the Knob** , as shown in Fig. 14-9.

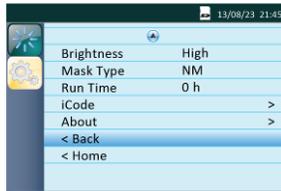


Fig. 14-9

Press **the Knob** , the cursor jumps to the second icon  on the left side of the screen. The screen displays the Initial Setup Interface, as shown in Fig. 14-10.



Fig. 14-10

(2) Returning to the Main Interface

Move the cursor to the **Home** option by turning **the Knob** , as shown in Fig. 14-11.



Fig. 14-11

Press **the Knob**  to exit the Patient Menu. The screen will display the Main Interface shown in Fig. 14-1 or Fig. 14-2.

14.2 Options of the Patient Menu and Corresponding Descriptions

Option	Range	Description
Humidifier	Off, 1 ~ 5	There are five humidity levels available. As the numbering increases, the humidity rises accordingly. "Off" means the humidifier is turned off. The default setting is "2"
Reslex	Off, 1 ~ 3	This feature enables the device to automatically reduce the treatment pressure when the patient exhales, so as to make the user more comfortable. The higher the numbering is, the more pressure the device reduces. "Off" means this feature is disabled. The default setting is "Off"
Ramp Time	0 - Max Ramp	In order to increase comfort and help the patient fall asleep easily, the pressure can increase gradually, when the Ramp feature is enabled. The ramp time during which the initial pressure rises to the prescribed treatment pressure can be adjusted. As you turn the Knob  to the nearest point, the numbering increases or decreases by five minutes. The default setting is "10 minutes." The screen displays a real-time countdown of the remaining ramp time in minutes
Delay	On / Off	When the humidifier is on, this feature allows the airflow to continue for about 15 minutes at a low pressure (about 2 hPa) after you press the Knob  to discontinue treatment. This will blow off the vapor left in the humidifier to avoid any damage to the device. When this feature is set to "Off," which means it is disabled, the airflow stops delivering air instantly after you press the Knob  . The default setting is "Off"
Date	2000-01-01 — 2099-12-31	Setting date by adjusting this option
Time	—	Setting time by adjusting this option
Brightness	High / Low	Setting screen brightness by adjusting this option. The default setting is "High"
Mask Type	FM; NM; PM; A, B, C	There are three mask types available, namely FM (full-face mask), NM (nasal mask), and PM (nasal pillow mask). The default mask type is "NM," but the patient can choose other suitable masks as well. When selecting masks other than the above three types of masks, the patient can identify the masks as A, B, or C
Run Time	0 ~ 50000 h	Run Time displays how long has the device been used by the user. The run time can be erased
iCode	iCode I, iCode II	iCode provides access to the patient's compliance data during a recent time period. The iCode I mode displays data in sequences of characters, and the iCode II mode displays data in two-dimensional codes

15. Alert

Alert Message	Description
Power Failure!!!	<p>An audible alert will sound if the device is accidentally disconnected from power when it is delivering air.</p> <p>Note:</p> <p>(1) The alert will not sound if power failure occurs when the device is in standby state.</p> <p>(2) No alert message on the screen during a power failure</p>
Device Fault!!!	<p>An audible alert will sound if no airflow comes out of the machine; the screen will display "Device Fault!!!!"</p>
Leak!!	<p>When the airflow is on, an audible alert will sound if the air leak rate exceeds 150 L/min; the screen will display "Leak!!"</p>
Low Input Voltage!!	<p>If you use a battery rather than an external power adapter to power the device, an audible alert will sound when the battery is low; the screen will display "Low Input Voltage!!"</p>
Humidifier Failure!!	<p>When humidifier is applied, an audible alert will sound when the humidifier fails to work; the screen will display "Humidifier Failure!!"</p>
Please Change Filter!	<p>When the Filter Alert feature is enabled, an audible alert will sound if an air filter has been used for more than six months; the screen will display "Please Change Filter!"</p>
SD Card Full!	<p>The screen will display "SD Card Full!" if the SD card has reached its maximum capacity</p>
Reinsert SD card!	<p>The screen will display "Reinsert SD card!" if the SD card fails to work</p>

16. Cleaning

WARNINGS!

- Regular cleaning of the device and its accessories is very important for the prevention of respiratory infections.
- To avoid electric shock, always unplug the device before cleaning.
- Use washing liquid that is nontoxic to humans and does not cause allergies in humans.
- Follow the manufacturer's instructions on cleaning the mask and air hose and on determining the frequency of cleaning.
- Before cleaning, check whether the device has been disconnected from the power supply, whether the power cord has been unplugged, and whether the water chamber of the humidifier has cooled down. Make sure the heater plate has cooled down to room temperature, so you do not get burned.
- The device shall not be serviced or maintained while in use with a patient.
- Sterilization of this device and its components other than recommended is not permitted.

CAUTIONS!

- Overheating of the materials could lead to early fatigue of these materials.
- Do not use solutions containing chlorinated lime, chlorine, or aromatic to clean the device and its accessories. Liquid soap containing the humidifying agent or antimicrobials should not be used either. These solutions may harden cleaned materials or reduce their life.
- Do not clean or dry the device and its accessories when the temperature is higher than 80°C (176°F). High temperatures could reduce product life.
- Do not immerse the device in any fluids.

16.1 Cleaning the Mask and Headgear

For details, refer to the cleaning instructions in the user manual for the mask.

16.2 Cleaning the Water Chamber of the Humidifier

For details, refer to the cleaning instructions in the user manual for the humidifier.

16.3 Cleaning the Enclosure

Wipe the surface of the device with a soft, slightly damp cloth.

CAUTION!

- The device can only be used after the enclosure is dry, so that no moisture enters the device.

16.4 Cleaning the Air hose

- (1) Remove the air hose from the device and mask before cleaning.
- (2) Clean the air hose in warm water which contains washing liquid, and then rinse it in clean water thoroughly.
- (3) After cleaning, air-dry the air hose in a cool, well-ventilated area, and avoid direct sunlight. It takes approximately 30 minutes to completely air-dry the air hose. Check whether the air hose is completely dry before re-use.

16.5 Replacing the Air Filter

- (1) Open the air filter cap to remove the air filter.
- (2) Put the new air filter in the filter area, and then place the filter cap back properly.

CAUTIONS!

- To avoid material damage, do not place the spare air filter in direct sunlight, humid environments, or temperatures below the freezing point. The air filter should be replaced every 6 months (It may be replaced more frequently based on actual sanitary conditions).
- Operating the device with a dirty air filter may stop it from working properly and may cause damage to the device.
- Replacing the air filter and filter cap, device must be unplugged.

17. Traveling with the Device

CAUTIONS!

- Empty the water chamber of the humidifier before packing the device for your trip; in order to prevent any remaining water from entering the device.
- Using the device at an incorrect elevation setting could result in airflow pressures higher than the prescribed setting. Always verify the elevation setting when traveling or relocating.
- If the device is used when the atmospheric pressure is out of the stated range (See Section 6), the accuracy of the leakage alert will be affected.

(1) Use the BMC carrying case to carry the device and accessories along with you. Do not put them in your checked baggage.

(2) This device operates on power supplies of 100 ~ 240 V and 50 / 60 Hz, and is suitable for use in any country in the world. No special adjustment is necessary, but you will need to find out the types of the power sockets in your destination. Bring, if necessary, a power socket adaptor which can be bought in electronics stores.

(3) Remember to bring a spare air filter and the emergency documents (filled and signed by your physician) about this device. If you plan to travel by air, remember to bring the multi-language emergency documents about respiratory therapy, in case that the border and customs officers in your destination country inspect the device. With the emergency documents, you can prove to them that it is a medical device.

(4) Security Stations: For convenience at security stations, there is a note on the bottom of the device stating that it is medical equipment. It may be helpful to bring this manual along with you to help security personnel understand the device.

18. Reordering

Contact your home care provider to order accessories or replacement filters. The device does not require routine servicing.

WARNINGS!

- If you notice any unexplained changes in the performance of the device, if it is making unusual or harsh sounds, if it has been dropped or mishandled, if the enclosure is broken, or if water has entered the enclosure, discontinue use. Contact your home care provider.
- If the device malfunctions, contact your home care provider immediately. Never attempt to open the enclosure of the device. Repairs and adjustments must be performed by 3B-authorized service personnel only. Unauthorized service could cause injury, invalidate the warranty, or result in costly damage.
- If necessary, contact your local authorized dealer or 3B Medical, Inc. for technical support and documents.

19. Technical Support

Please contact 3B directly if you need the circuit diagram of the device and the list of components for certain purposes such as maintenance or connection to other equipment. 3B will provide the circuit diagram and / or other technical documents in whole or in part according to your needs.

20. Disposal

When the device reaches the end of its service life, dispose of the device and packaging in accordance with local laws and regulations.

21. Troubleshooting

The table below lists common problems you may have with the device and possible solutions to those problems. If none of the corrective actions solve the problem, contact your home care provider.

21.1 Common Problems in Patients and Corresponding Solutions

Problem	Possible Cause	Solution (s)
Dry, cold, runny, and blocked nose; having a cold	The nose reacts to the airflow and cold. Due to fast airflow, the air becomes cold, leading to nasal mucosa irritation and subsequent dryness and swelling	Increase the humidity setting of the humidifier. Contact your physician, and continue treatment unless the physician suggests the opposite
Dry mouth and throat	Probably because the patient sleeps with his or her mouth open, and the pressurized air goes out via the mouth, leading to nasal and throat dryness	Use a chin strap to prevent the mouth from opening during sleep, or use a full-face mask. Contact your physician for details
Eye irritation	The mask size or model may not be correct, or the mask is not positioned correctly, thereby leading to air leakage	Narrow the distance between the forehead support of the mask and the forehead. Note that adjusting the mask too tight may leave markings on the patient's face. Add additional filling to the mask so it does not leak. Contact your equipment supplier for an appropriate mask. Add additional filling to the mask if necessary
	Mask cushion (the soft part of the mask) hardens	Replace the mask or mask cushion
Facial reddening	The mask is too tight	Loosen the headgear
	The distance between the forehead support of the mask and the forehead is not correct	Try a different distance. The angle and size of the forehead support differ according to the type of masks
	Wrong mask size	Contact your equipment supplier for a correct-size mask

	The patient is allergic to the materials of the mask	Contact your physician and equipment supplier. Use a mask which is not made with natural rubber latex. Place a lining between the skin and mask
Water in mask	When the humidifier is used, the humidified air tends to condense in the cold air hose and mask if the room temperature is low	Turn the humidity setting down, or raise the room temperature. Place the air hose under the quilt, or use the air hose cover. Hang the air hose loosely, and the lowest part of the air hose should be lower than the patient's head
Nasal, sinus, or ear pain	Sinus or middle ear inflammation	Contact your physician immediately
Discomfort due to inability to adapt to the treatment pressure	The patient will feel uncomfortable when the treatment pressure is higher than 13 hPa. However, the treatment pressure is determined according to the patient's conditions, and cannot treat sleep apnea if the treatment pressure is set too low	It takes a maximum of four weeks to adapt to pressurized air. Relax and breathe through the nose. If the problem still exists, contact your physician
Obstructive sleep apnea symptoms recur	Probably because the patient sleeps with his or her mouth open, and the pressurized air goes out via the mouth, leading to blockage in the respiratory tract	Use a chin strap to prevent the mouth from opening during sleep, or use a full-face mask. Contact your physician for details
The device is too noisy	The air hose is not connected properly	Reconnect the air hose properly
Air delivered from the device is abnormally hot	The air inlet of the device may be partially blocked, leading to insufficient airflow into the device	Replace the air filter (see 16.5 Replacing the Air Filter), and clean the air inlet Place the device in an area where air flows freely, and make sure the device is at least 20 centimeters away from the wall, curtain, or other things

21.2 Common Problems in the Device and Corresponding Solutions

Problem	Possible Cause	Solution (s)
The device does not work when it is turned on	The Auto On / Off feature is enabled	Take a few deep breaths with the mask on, and the device will start automatically
	Power is not connected properly	Ensure that the power cord, power adapter, and the device are connected properly
	There is no voltage	Check whether a power outage occurs by turning on a light or other means. If you are sure the fuse in the device is broken, contact your equipment supplier for repair
	Cannot find any cause	Contact your equipment supplier
The device is working, but the pressure inside the mask differs from the set treatment pressure	The air hose is not connected properly	Reconnect the air hose properly
	There may be holes in the mask or pressure sensing air hose	Contact your equipment supplier
	It is a faulty device	Contact your equipment supplier
The device produces very low pressures	The air inlet of the device may be blocked	Replace the air filter (see 16.5 Replacing the Air Filter), and clean the air inlet. Make sure the air inlet is unblocked
	The treatment pressure has been changed accidentally	Contact your physician
	When the Ramp feature is enabled, it takes some time for the initial pressure to rise to the treatment pressure. This is normal	If necessary, disable the Ramp feature, or set the ramp time shorter
After the device is turned on, the screen displays intermittently, or displays nothing at all	The operating system of the device needs to be readjusted or restarted	Unplug the power cord of the device, and re-plug it 20 seconds later
The device is in standby, and will not start	The operating system of the device needs to be readjusted or restarted	Unplug the power cord of the device, and re-plug it 20 seconds later

22. EMC Requirements

Guidance and manufacturer's declaration - electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The user of the device should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for Input / output lines	± 2 kV for power supply lines ± 1 kV for Input / output lines	Mains power quality should be that of a typical home or hospital
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical home or hospital
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$< 5\% U_T$ ($> 95\%$ dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $< 5\% U_T$ ($> 95\%$ dip in U_T) for 5 s	$< 5\% U_T$ ($> 95\%$ dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $< 5\% U_T$ ($> 95\%$ dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or from a battery
Power frequency (50 / 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	If the pressure deviates more than is indicated in the device specifications, it may be necessary to position the device further from sources of power frequency magnetic fields. The power frequency magnetic field should be measured in the intended installation location to ensure that it is sufficiently low
Note: U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
Note 1: At 80 MHz and 800 MHz, the higher frequency range applied.			
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.			
^b Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the device

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

Rated maximum output of transmitter W	150 kHz ~ 80 MHz $d = 1.2\sqrt{P}$	80 MHz ~ 800 MHz $d = 1.2\sqrt{P}$	800 MHz ~ 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

23. Limited Warranty

3B Medical, Inc. warrants that the Luna® E-20 models will be free of all defects in workmanship and materials, and will perform according to specifications, for a period of two (2) years of sale from the sale of the device.

If the product fails to perform in accordance with the product specifications, 3B Medical, Inc. will repair or replace, at its option, the defective material or part. This warranty does not cover damage caused by accident, misuse, abuse, alteration and other defects not related to material or workmanship.

- 3B will issue an RMA (Return Merchandise Authorization) within 24 hours of receipt of written notification of a failed or defective unit. Failed / defective units must be returned within 30 days of the RMA date.
- This warranty coverage is applicable to all 3B / BMC CPAP, Auto-CPAP and Auto Bi-Level devices.
- The warranty policy does not cover any damages caused as a result of alteration, intentional damage, modification, or unauthorized repair of the device.
- 3B reserves the right to amend this policy at any time.

To exercise the rights under this warranty, contact your local authorized dealer or:

3B Medical, Inc.
21301 US Highway 27 N
Lake Wales, FL 33859
T: (863) 226-6285
F: (863) 226-6284

For additional information, please visit our Patient Portal at:
www.3bproducts.com
icodeconnect.com – Web-based cloud for report generation and storage
www.bmc-icode.com – Website for iCode data report retrieval



H60 Heated Humidifier

User Manual



The H60 Heated Humidifier is designed only for use with specific Luna® E-20A and E-20C Series devices. Do not use the H60 Heated Humidifier with any other devices.

The humidifier moistens the air delivered by the Luna® E-20A and E-20C Series devices. It is for use in the home or hospital / institutional environment.

The H60 Heated Humidifier is only used for single patient and must not be re-used on another person. This is to avoid the risk of cross-infection.

The H60 Heated Humidifier is not intended for use with a patient whose upper airway has been bypassed.

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1. Warning, Caution and Important Tip

WARNING!

Indicate the possibility of injury to the user or operator.

CAUTION!

Indicate the possibility of damage to the device.

IMPORTANT TIP!

Place emphasis on an operating characteristic.

Warnings, Cautions, and Important Tips appear throughout this manual as they apply.

2. Symbols



Operating Instructions



Type BF Applied Part



Class II (Double Insulated)



AC Power



DC Power

IP22 ≥ 12.5 mm Diameter, Dripping (15° tilted)



Hot Surface



Serial Number of the Product



Manufacturer



0123 European CE Declaration of Conformity



Water Filling Prohibited Here



Water Inlet



Directional Indicator for Removing the Water Inlet Cap



Directional Indicator for Screwing the Water Inlet Cap

3. Features

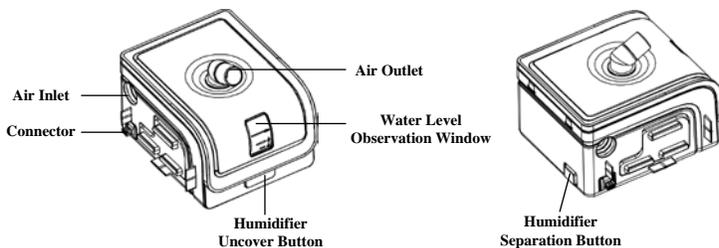


Fig. 3-1

Name	Function
Air Inlet	Connect to the outlet of the main device
Air Outlet	Deliver humidified air to the patient; connect to the air tubing
Connector	Heat the water in the water chamber and detect the temperature
Water Level Observation Window	Observe the water level in the water chamber
Humidifier Uncover Button	Press this button to open the top cover of the humidifier
Humidifier Separation Button	Press this button to separate the humidifier from the main device

4. Daily Use

IMPORTANT!

- Never operate the humidifier if any of its parts are damaged, if it is not working properly, or if the humidifier has been dropped or mishandled. Do not use the humidifier if the water chamber is leaking or damaged in any way. Have any damaged parts replaced before continuing use.
- Read all instructions before using the humidifier.
- Use only with BMC devices whose instructions specify the use of this humidifier.
- Please use the mask which meets ISO17510-2:2009.

CAUTIONS!

- This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- Do not operate the device in direct sunlight or near a heating appliance because these conditions can increase the temperature of the air coming out of the device.
- When humidifier is used outside the specified ambient temperature range or humidity range, the performance of humidifier will be compromised.

- U.S. federal law restricts this device to sale by or on the order of a physician.

WARNINGS!

- Use the humidifier only for its intended use as described in this manual.
- Use only accessories recommended by BMC.

4.1 Connecting, Separating the Humidifier and Main Device

4.1.1 Connecting the Humidifier to the Main Device

Remove the shield from the main device, following the steps below:

- (1) Overturn the main device and find the buckle slot at the bottom of the main device, as shown in Fig. 4-1.
- (2) Remove the shield by inserting a flat tool into the buckle slot.

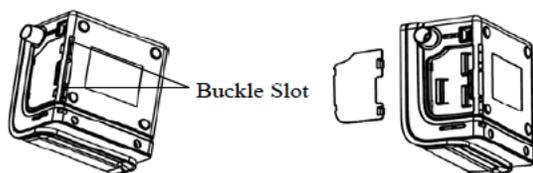


Fig. 4-1

After the shield is removed, place the humidifier and main device near each other as shown in Fig. 4-2. The air outlet of the main device should be targeted to the inlet of the humidifier. Push the two devices together until they click into place. Fig. 4-2 shows their positions before and after connection to each other.

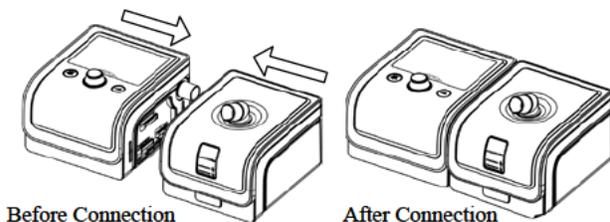


Fig. 4-2

CAUTION!

- When the main device delivers air and the humidity setting is adjusted, if the indicator lights of the humidifier do not light up, it may be that the humidifier and main device are not connected correctly.

4.1.2 Separating the Humidifier from the Main Device

Press the **Humidifier Separation Button** on the humidifier and, at the same time, pull the humidifier and main device apart in opposite horizontal directions, as shown in Fig. 4-3.

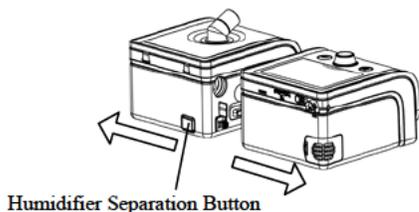


Fig. 4-3



Fig. 4-4

CAUTIONS!

- Do not move the connected unit upwards or downwards while pulling the devices apart (see Fig. 4-4). It could cause damage to the devices.
- Place the shield back on the main device when the humidifier is not in use.

4.2 Filling the Water Chamber

4.2.1 Removing the Water Chamber

Press the **Humidifier Uncover Button** to open the top cover. Hold the front center of the humidifier with your thumb and index finger, and pull the chamber out of the humidifier, as shown in the figure below.

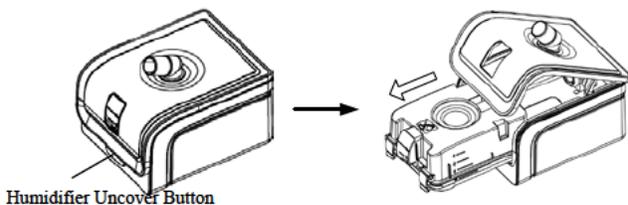


Fig. 4-5

WARNING!

- Turn the device off and allow approximately 15 minutes for the heater plate and water to cool.

4.2.2 Overturning the Water Chamber

Turn the water chamber over so that it is bottom up, as shown in the figure below.

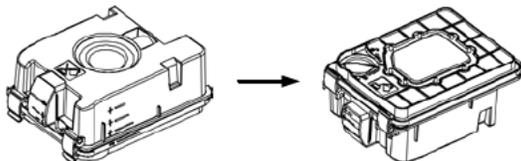


Fig. 4-6

WARNINGS!

- Never touch the heater plate unless the humidifier is unplugged and the plate has cooled down.
- Fill the water chamber only after it is turned over, otherwise the device could be damaged.

4.2.3 Removing the Water Inlet Cap

Turn the water inlet cap counterclockwise so the arrowhead on the cap points to the triangle symbol \blacktriangle , and then remove the cap.

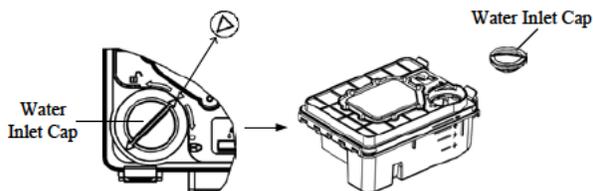


Fig. 4-7

4.2.4 Filling Water

Fill the water chamber with approximately 350 ml of water through the water inlet. Make sure that the water does not exceed the maximum water level line. Observe the water level in the water chamber through the Water Level Observation Window.

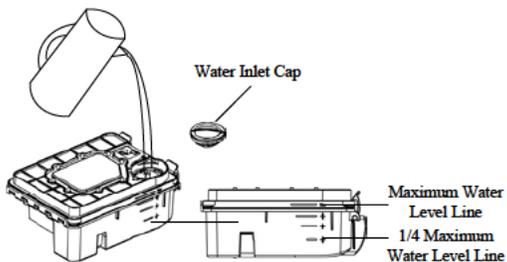


Fig. 4-8

WARNING!

- Every time before treatment, be sure to drain any residual water out of the water chamber, and ensure the maximum water level line is not submerged by water.

CAUTIONS!

- Empty the water chamber when the humidifier is not in use.
- Distilled water is recommended.

4.2.5 Returning the Water Chamber

Put the cap back on the water chamber after it is filled with water. Turn the cap clockwise until the arrowhead on the cap points to the round symbol . Overturn the water chamber and return it to the humidifier.

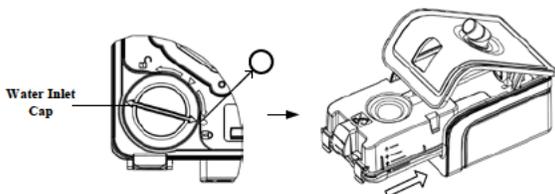


Fig. 4-9

WARNING!

- For safety purposes, the filled humidifier must be placed on a flat surface at a level lower than the patient's head when he or she lies down on a bed, so that the condensation flows back to the water chamber rather than remain in the tubing inhibiting breathing.

CAUTIONS!

- Avoid moving or tilting the humidifier when the water chamber has water in it.
- Do not turn the humidifier on without the water chamber installed.
- Take precautions to protect furniture from water damage.

4.3 Emptying the Water Chamber

(1) Remove the water chamber according to instructions in 4.2.1.

(2) **Empty the water chamber:** Separate the main body of the water chamber from the chamber base, and pour any remaining water out of the main body of the water chamber. Undo the **Water Chamber Buckle**, and open the water chamber as shown below.

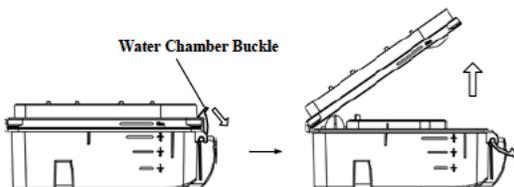


Fig. 4-10

CAUTION!

- Empty and air-dry the water chamber when the humidifier is not in use.

(3) Assemble the water chamber: Place the main body of the water chamber on a level surface, and then insert the chamber base into the main body of the water chamber and fasten the **Water Chamber Buckle**, as shown in the figure below.

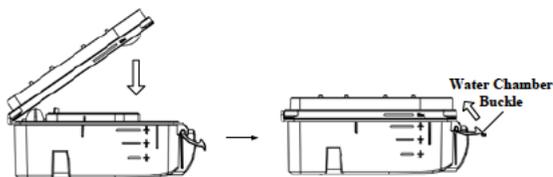


Fig. 4-11

4.4 Setting the Humidity Level

After the main device is powered on, turn the **knob**  to turn on or turn off the humidifier and to adjust the humidity level according to instructions on the screen of the main device.

There are five humidity levels available, and the number of blue indicator lights that light up is directly proportional to the humidity level. If none of the indicator lights light up, it means that the humidifier is turned off.

The temperature of the water in the water chamber maintains a constant set level. Three indicator lights light up when the humidity is adjusted to Level 3, as shown in Fig. 4-12.

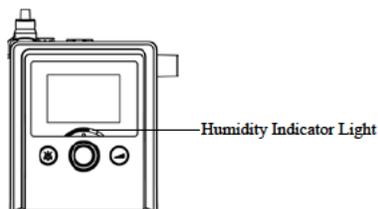


Fig. 4-12

CAUTIONS!

- Generally speaking, the humidity inside the mask is low when the water temperature is low.
- The greater the difference between the temperature inside the air tubing and room temperature is, the more easily condensation occurs inside the tubing.
- If there are only a few condensed water droplets inside the tubing in the morning after therapy, it means that the humidity level is proper; if there are lots of condensed water droplets inside the tubing and / or mask, it means that the humidity level is too high and should be set lower; Nasal dryness means that the humidity level is too low and should be set higher.

WARNING!

- Do not touch the heater plate of the humidifier when it is working, otherwise you may get burned. Turn off the heater plate when the humidifier is not in use.

5. Cleaning

Clean the water chamber before first use of the humidifier or at least once every week. If the humidifier has not been in use for a long time, clean the water chamber before reusing it.

WARNING!

- To avoid electrical shock, disconnect the power cord of the device before cleaning the humidifier. DO NOT immerse the humidifier in any fluids.
- The device shall not be serviced or maintained while in use with a patient.
- Sterilization of this device and its components other than recommended is not permitted.

CAUTIONS!

- Do not use solutions containing chlorinated lime, chlorine, or aromatic to clean the device and its accessories. Liquid soap containing the humidifying agent or antimicrobials should not be used in cleaning either. These solutions may harden cleaned materials or reduce their life.
- Do not clean or dry the device and its accessories when the temperature is higher than 80°C (176°F). High temperatures could reduce product life.

5.1 Separating the Humidifier Top Cover from its Main Body

Press the **Humidifier Uncover Button** to lift and open the top cover of the humidifier. Continue to lift the top cover until it separates completely from the main body of the humidifier, as shown in the figure below.

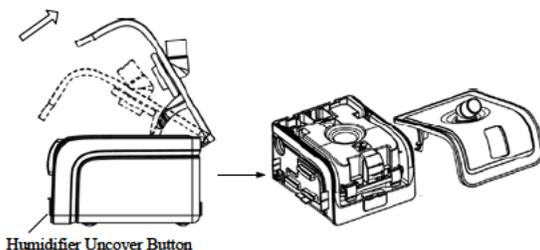


Fig. 5-1

5.2 Removing the Water Chamber

Pull the water chamber out of the main body of the humidifier horizontally, as shown in the figure below.

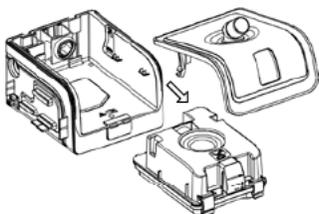


Fig. 5-2

5.3 Detaching the Air-intake Assembly

After the water chamber is removed, detach the **air-intake assembly** from the main body of the humidifier by pulling it upwards, as shown in the figure below.

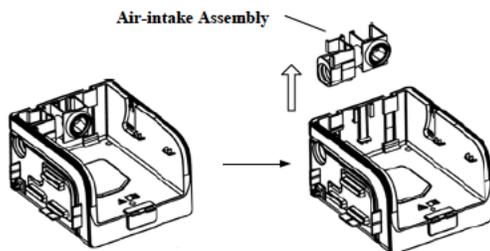


Fig. 5-3

5.4 Cleaning the Water Chamber

WARNINGS!

- Emptying and cleaning the water chamber daily will help prevent mold and bacteria growth.
- Allow the water in the chamber to cool down to room temperature before removing it from the humidifier.

CAUTIONS!

- Clean the water chamber only after the water in it cools. Make sure that no water enters the main device.
- After cleaning, rinse all parts thoroughly in clean water to make sure that no washing liquid is left; then wipe all parts dry with a lint-free cloth, so as to prevent calcareous accumulations.
- Inspect the water chamber for any leak or damage. Replace the water chamber if any damage is present.

(1) Opening the Water Chamber: Undo the **water chamber buckle** and then open the water chamber.

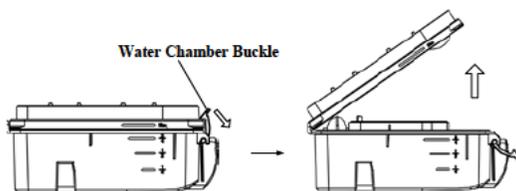


Fig. 5-4

(2) **Cleaning the Water Chamber:** Wash the two parts of the water chamber, as shown in Fig. 5-5. You may also clean them with a scouring pad (dip the scouring pad in washing liquid if necessary), rinse them thoroughly, and then wipe them dry with a soft cloth.

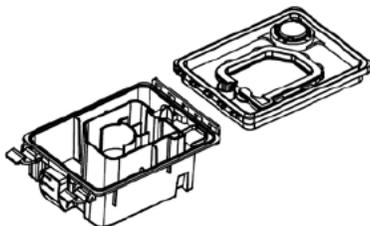


Fig. 5-5

(3) **Assembling the Water Chamber:** Place the two parts of the water chamber together as shown in Fig. 5-6. Press hard until they click into place.

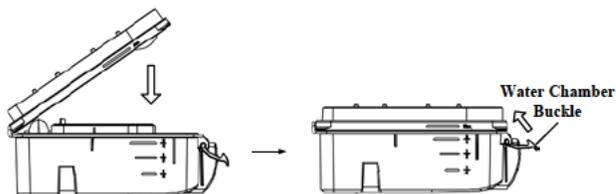


Fig. 5-6

5.5 Cleaning the Air-intake Assembly

First remove the sealing elements from the air-intake assembly, and then clean the air intake and sealing elements separately with running water, as shown in the figure below. They can also be cleaned with a scouring pad (dip the pad in mild scrubbing solutions if necessary), and then rinsed thoroughly. Wipe the air intake with soft cloth, and allow the sealing elements to air dry.

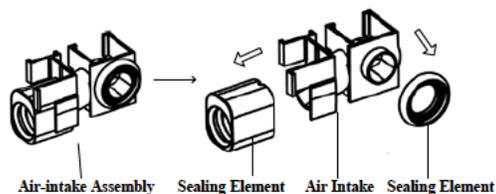


Fig. 5-7

5.6 Cleaning the Top Cover and Main Body of the Humidifier

Clean the top cover and main body of the humidifier separately with running water, as shown in the figure below. They can also be cleaned with a scouring pad (dip the pad in mild scrubbing solutions if necessary), then rinsed thoroughly, and at last wiped with soft cloth.

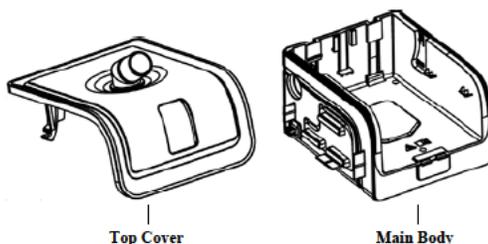


Fig. 5-8

5.7 Reassembling the Humidifier

(1) Set up the air-intake assembly: First install the sealing elements to the air intake, as shown in the figure below.

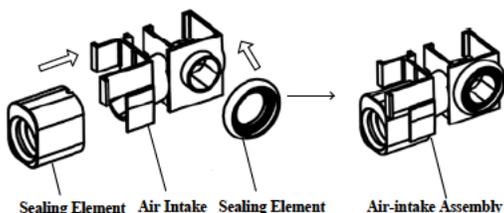


Fig. 5-9

(2) Then install the air-intake assembly back to the main body of the humidifier, as shown in the figure below.

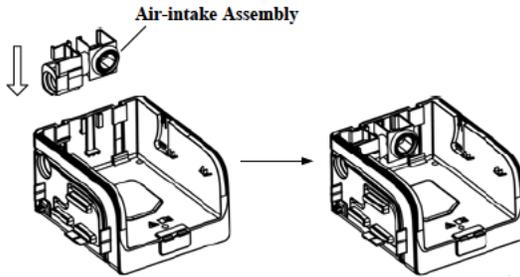


Fig. 5-10

(3) Return the water chamber to the main body of the humidifier, as shown in the figure below.

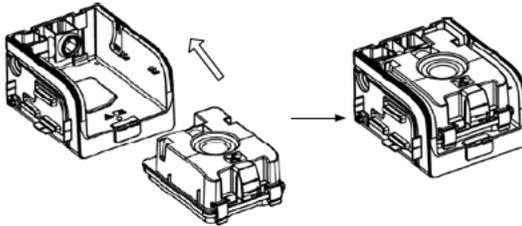


Fig. 5-11

(4) Connect the top cover and main body of the humidifier properly, as shown in the figure below.

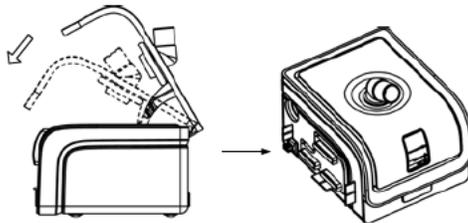


Fig. 5-12

6. Service

The humidifier does not require routine servicing.

If the humidifier malfunctions, contact your home care provider immediately. Never attempt to open the humidifier's enclosure. If necessary, contact your local authorized dealer or BMC Medical Co., Ltd. for technical support and documents.

7. Specifications

Size

Dimensions: 120 mm × 196 mm × 134 mm

Weight: < 1 kg

Water Capacity: 350 ml at recommended water level

Product Use, Transport and Storage

	Operation	Transport and Storage
Temperature:	5°C to 35°C (41°F to 95°F)	-25°C to 70°C (-13°F to 158°F)
Humidity:	15% to 93% Non-condensing	15% to 93% Non-condensing
Atmospheric Pressure:	760 to 1060 hPa	760 to 1060 hPa

Power Requirements(when the heated humidifier is used with the main device.)

100 ~ 240 V AC, 50 / 60 Hz, 2.0 A max.

Type of Protection Against Electric Shock

Class II Equipment

Degree of Protection Against Electric Shock

Type BF Applied Part

Degree of Protection Against Ingress of Water

IP22

Heater Settings

1 to 5 (95°F to 167°F / 35°C to 75°C)

Maximum Operating Pressure

30 hPa

Pressure Drop with Humidifier

< 0.4 hPa at 60 LPM flow

Humidifier Performance

Humidity Output: No less than 10 mg H₂O/L

Environmental Conditions: Maximum airflow, 35°C, 15% relative humidity

Maximum Delivered Gas Temperature

< 43°C

The Form and the Dimensions of the Patient Connection Port

The 22 mm conical air outlet complies with ISO 5356-1

8. Disposal

When necessary, dispose of the device and accessories in accordance with local laws and regulations.

9. Traveling with the System

Packing the System

- (1) Remove the water chamber and pour out all water.
- (2) Return the empty water chamber to the humidifier.
- (3) Put the humidifier in your carry-on bag.

When traveling, the optional carrying case is for carry-on luggage only. The carrying case will not protect the humidifier if it is put through checked baggage.

Security Stations

For ease at security stations, there is a note on the bottom of the humidifier stating that it is medical equipment. It may be helpful to bring this manual along with you for security personnel.

10. EMC Requirements

Guidance and manufacturer's declaration - electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The user of the device should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	± 2 kV for power supply lines ± 1 kV for input / output lines	Mains power quality should be that of a typical home or hospital
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical home or hospital
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$< 5\% U_T$ ($> 95\%$ dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $< 5\% U_T$ ($> 95\%$ dip in U_T) for 5 s	$< 5\% U_T$ ($> 95\%$ dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $< 5\% U_T$ ($> 95\%$ dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or from a battery
Power frequency (50 / 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	If the pressure deviates more than is indicated in the device specification, it may be necessary to position the device further from sources of power frequency magnetic fields. The power frequency magnetic field should be measured in the intended installation location to ensure that it is sufficiently low
Note: U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3\sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
<p>Note 1: At 80 MHz and 800 MHz, the higher frequency range applied.</p> <p>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> <p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.</p>			

Recommended separation distances between portable and mobile RF communications equipment and the device

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

Rated maximum output of transmitter W	150 kHz ~ 80 MHz $d = 1.2\sqrt{P}$	80 MHz ~ 800 MHz $d = 1.2\sqrt{P}$	800 MHz ~ 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

11. Warranty

BMC Medical Co., Ltd. warrants that this humidifier shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of one (1) year from the date of sale by BMC Medical Co., Ltd. to the dealer. If the product fails to perform in accordance with the product specifications, BMC Medical Co., Ltd. will repair or replace, at its option, the defective material or part. BMC Medical Co., Ltd. will pay customary freight charges from BMC Medical Co., Ltd. to the dealer location only. This warranty does not cover damage caused by accident, misuse, abuse, alteration and other defects not related to material or workmanship.

To exercise your rights under this warranty, contact your local, authorized dealers or:

MANUFACTURER:

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