Y-30T

(Target Tidal Volume Function)

Non-invasive ventilator Y-30T is Bi-level PAP (Bi-level Positive Airway Pressure) device intended to provide non-invasive ventilation for patients with Respiratory Insufficiency. It is intended for adult patients by prescription in the home or hospital/institutional environment. With its Target Tidal Volume function and other excellent comfort features and effective performance, it offers each patient personalized ventilation support.

Clinical Results

The following recommendations pertain to adult and paediatric patients with ARDS who are treated with non-invasive or high-flow oxygen systems.

High-flow nasal oxygen (HFNO) should be used only in selected patients with hypoxemic respiratory failure.

Non-invasive ventilation (NIV) should be used only in selected patients with hypoxemic respiratory failure.

Patients treated with either HFNO or NIV should be closely monitored for clinical deterioration.

--Reference *Clinical management of severe acute respiratory infection (SARI) when COVID-19 disease is suspected*

Treatment of severe and critical cases:

a. Treatment principle:

Based on symptomatic treatment, actively prevent complications, treat basic diseases, prevent secondary infections, and provide organ function support in a timely manner

b. Respiratory support:

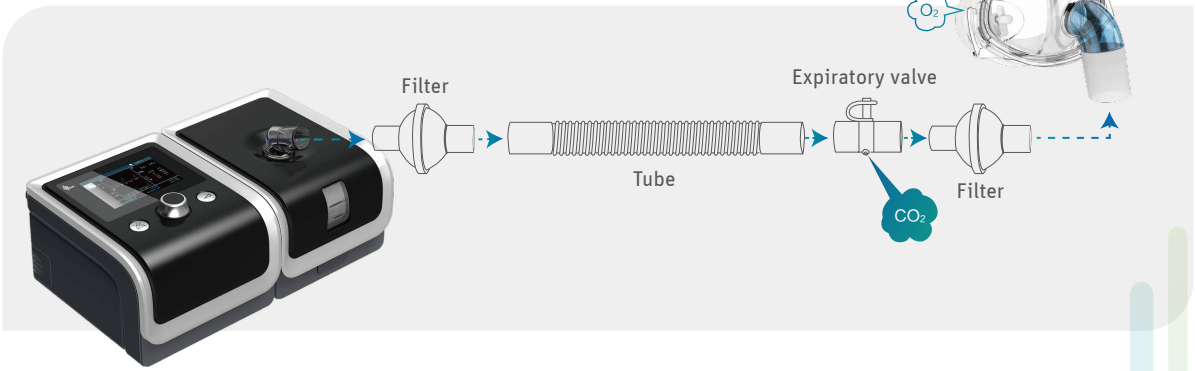
(a) Oxygen therapy: Severe patients should receive nasal cannula or mask to inhale oxygen and evaluate in time whether respiratory distress and / or hypoxemia is relieved.

(b) High-flow nasal cannula oxygen therapy or non -invasive mechanical ventilation: When patients have respiratory distress and / or hypoxemia cannot be relieved after receiving standard oxygen therapy, high -flow can be considered Nasal catheter oxygen therapy or non-invasive ventilation. If the condition does not improve or worsens within a short time (1 to 2 hours), tracheal intubation and invasive mechanical ventilation should be performed in time.

-- Reference *Diagnosis and treatment of pneumonitis for a new coronavirus infection (Trial Version 7)*

How to avoid nosocomial infections with non-invasive

Filter needs to pay attention to the problem of increased resistance to water overload.
The increased resistance needs to be replaced at any time!



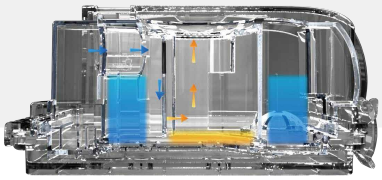
Y-30T Non-invasive ventilator
with humidifier

-- Reference *Chinese Journal of Respiratory and Critical Care medicine, Feb. 2020, Vol. 19, No. 2*

Comfortability

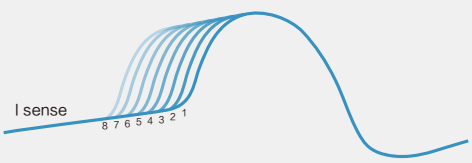
Humidifier

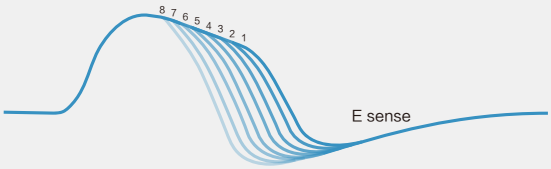
- Eco Smart heating system with innovative dual water chambers design delivers accurate water quantity control with real time compensation, ensuring excellent humidifying capacity and improves comfort.
- Easy to take off and clean.
- Function to prevent overheating when water is out.



Inspiratory / Expiratory sensitivity

8 grades of I Sens and E Sens optimize the compliance of machine with the patient.

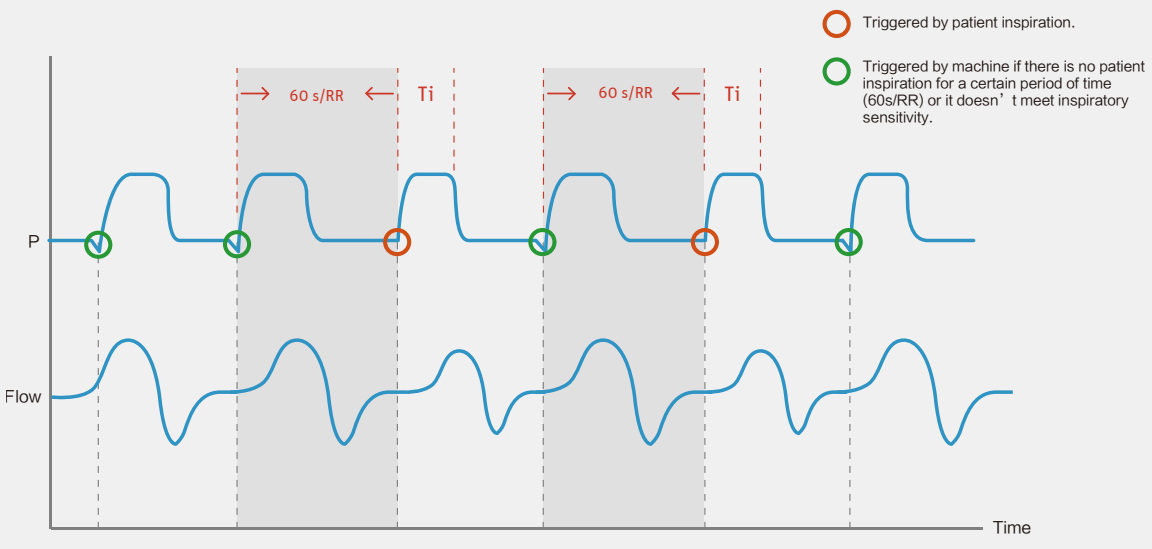




Efficiencies in Therapy

S/T Mode

Machine complies with patient breathing. However, if there is no inhalation for a certain period of time, the machine will give a forced ventilation to ensure the minimum ventilation.

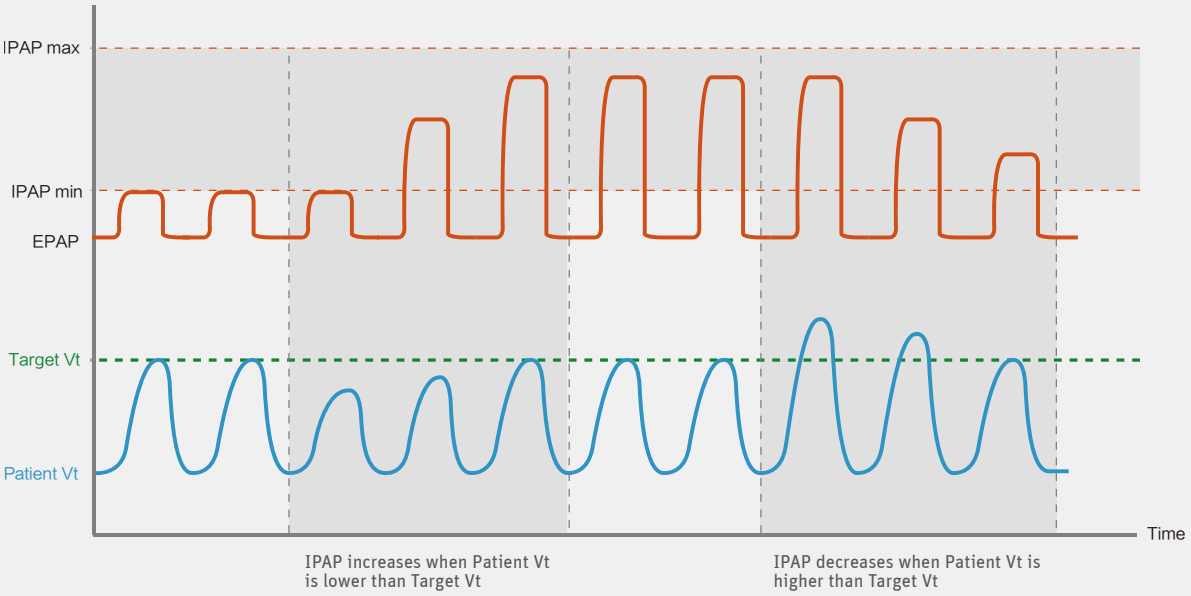


Target Tidal Volume Function

Optimize IPAP according to mean Vt of last 5 breathings and prescribed Target Vt. Larger difference between mean Vt and target Vt takes more evident adjustment in IPAP.

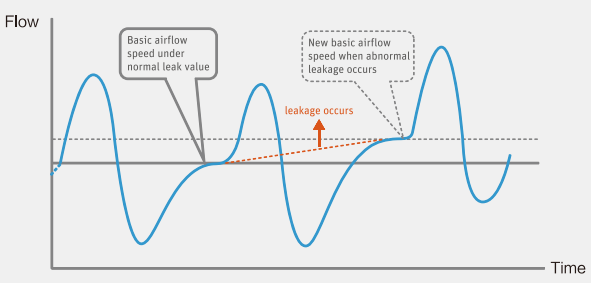
- Inspiratory pressure is between IPAP min and IPAP max.
- Larger difference between mean Vt and target Vt takes more evident adjustment in IPAP.
- Patient Vt is the mean of Vt values from patient's last 5 breathings.

Height (m)	Ideal Weight (kg) (BMI=20)	Target Vt (mL) (8 mL/kg)	Target Vt (mL) (10 mL/kg)
1.50	45	360	450
1.55	48	380	480
1.60	51	410	510
1.65	54	440	540
1.70	58	460	580
1.75	61	490	610
1.80	65	520	650
1.85	68	550	690
1.90	72	580	720



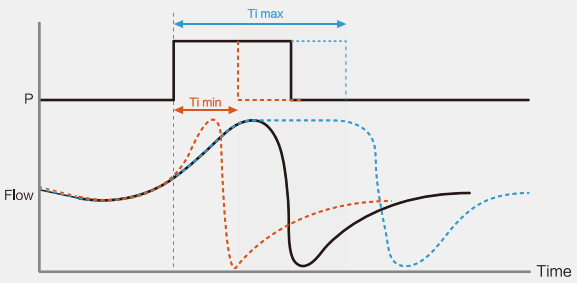
Auto Leak Compensation

The machine detects the leaks during treatment in real time and adjusts the baseline to ensure correct triggering and related functions.



Inspiratory time control

Tim min and Ti max could be set independently, avoiding insufficient ventilation due to short inspiratory time. At the meantime, cases can be prevented where expiratory sensitivity is unable to meet due to large leaks.



User Friendliness

Data Management

SD Card | GPRS | Wi-Fi | iCode / iCode QR / iCode QR+

Various way of therapy report review

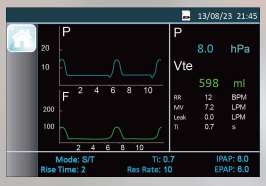
- Quick Report through Device Screen
- BMCares App
- BMCares Cloud Platform
- iCode web version (www.bmc-icode.com)
- RESmart nPAP Data Analysis Software (PC software)
- RESmart Software web version (www.icodeconnect.com/quick/info)

Alarms to make therapy reliable

Various visual and auditory alarming - Leak, High/Low RR, High/Low Pressure, Low Minute Ventilation, Low SpO_2, Power Failure, etc.

3.5-inch LCD screen

Real time display - Pressure (waveform), Flow (waveform), Vte, Respiratory Rate, Minute Ventilation, Leak, Inspiration Time.



15 languages

English / Español / Português / Deutsch / 中文（简体） / Français / Polski / Italiana / Türk / Русский / Nederlands / Ελληνικά / 한국어 / Magyar / ไทย

Full therapy solution

- Trolley
- Battery for power back-up
- Respiratory humidifier to deliver optimal outcomes
- 15 or 22 mm tubing
- Heated tubing
- SpO_2 Kit
- GPRS / Wi-Fi Kit
- 12/24 V DC/DC Converter

*Some parts are not produced by BMC

Benefits of monitoring & supporting through cloud platform and patient self-management

A 12-month study in the United States in disease management such as strengthened education, follow-up in patients with chronic obstructive pulmonary disease, showed that:
Reduction in hospital admission and emergency visits for COPD, particularly for cases due to non-infectious factors.

Am J Respir Crit Care Med. 2010 Oct 1;182(7):890-6

Dewen and other studies have found that multi-dimensional integrated management in patients can effectively reduce the medical cost of COPD by about 11.7% per person.

COPD.2011 Jun;8(3):153-9

*Studies and researches above are listed as clinical references only, which were not conducted with BMC products.

Specifications

Model Comparison

Y-30T	IPAP: 4 - 30 hPa EPAP: 4 - 25 hPa CPAP mode: 4 - 20 hPa	3.5-inch	CPAP, S, T, S/T

General Info

Dimensions: 170 mm × 180 mm × 118 mm
290 mm × 180 mm × 134 mm (with the humidifier)
Weight: 1.5 kg
2.5 kg (with the humidifier)
Water capacity: 350 mL at recommendedwater level

Ramp

The ramp time ranges from 0 to 60 minutes

Humidifier

Humidifier Settings: off, 1 to 5 (95°F to 167°F / 35°C to 75°C)
Humidifier Output: No less than 10 mg H20/L

SpO_2

Range: 0 to 100%

Pulse Rate

Range: 40 to 240 BPM

Sound Pressure Level

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

Storage

SD card can record patient data and fault information

AC Power Consumption

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

Key Parameters

Target Vt: On/ Off
150~1500 mL
Reslex: Patient, Off, 1~3
I Sens.: 1~8
E Sens.: 1~8
Res Rate: 3~40 BPM
Ti: 0.3-3.0s
Rise Time: 1~4

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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 081775 0008 Rev. 02

Manufacturer:

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Room 110 Tower A Fengyu Building, No. 115 Fucheng Road
Haidian
100036 Beijing
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

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BMC (Tianjin) Medical Co., Ltd.
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Tianjin, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Masks; Tubes; Sleep Apnea Therapy Devices, Respiratory Insufficiency Ventilators and Accessories: CPAP, Auto CPAP, BPAP, Humidifier; Heated Humidifier and Accessories: Humidifier, Water Chamber, Nasal Cannula and Tubes; Sleep Apnea Diagnosis Devices and Accessories: Sleep Screener, Polysomnograph, Portable Sleep Diagnostic System.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: BJ19963043

Valid from: 2020-01-20
Valid until: 2023-03-31

Date, 2020-01-20

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

FDA

Appendix B: Authorized Ventilators, Ventilator Tubing Connectors, and Ventilator Accessories
Updated: April 6, 2020

To be added to **Appendix B** (below), ventilators, ventilator tubing connectors, and ventilator accessories must be determined to meet the applicable conditions and criteria for safety, performance and labeling set forth in Section II, Section IV, and Appendix A. FDA will add a ventilator, ventilator tubing connector, and ventilator accessory to the list of authorized products in **Appendix B** (below) upon submission of a request from a sponsor as described in the Scope of Authorization Section of the Letter of Authorization (Section II) and pursuant to the Conditions of Authorization (Section IV) in this EUA and based on FDA's review and concurrence.

Ventilators

Manufacturer	Product Name	Device Description	Intended Use	Date of Authorization
BMC Medical Co., Ltd.	Y-30T	Ventilator, Continuous, Minimal Ventilatory Support, Facility Use	BPAP System (Y-30T Model) is a Bi-level PAP (Bi-level Positive Airway Pressure) device, which is intended to provide non-invasive ventilation for patients with obstructive Sleep Apnea (OSA) and Respiratory Insufficiency. Y-30T device is intended for adult patient by prescription in the home or hospital/institutional environment. This device is not intended for life support. The optional Heated Humidifier used with the Y-30T device together is indicated for taking humidifying and heating air from the device.	April 2, 2020

BMC Certificates for COVID-19

The following recommendations pertain to adult and paediatric patients with ARDS who are treated with non-invasive or high-flow oxygen systems.
High-flow nasal oxygen (HFNO) should be used only in selected patients with hypoxemic respiratory failure.
Non-invasive ventilation (NIV) should be used only in selected patients with hypoxemic respiratory failure.
Patients treated with either HFNO or NIV should be closely monitored for clinical deterioration.

--Reference *Clinical management of severe acute respiratory infection (SARI) when COVID-19 disease is suspected*

Registration

FDA +CE, Mexico, Argentina, Australia, Israel, Saudi Arabia

Non-invasive ventilator Y-30T

Therapeutic product for COVID-19 patients

- 15 languages, covering most languages in COVID-19 areas
- Real-time monitoring: pressure, blood oxygen, and respiratory rate
- Tidal volume is monitored and target tidal volume can be set
- Scan the iCode QR to view the daily generated treatment data

- Mode: CPAP, S, S/T, T
- Pressure: 4-30 cmH_2O
- I/E sense: 8
- Ramp time: 1-4
- Res rate: 3-40 BPM
- Target volume: 150-1500 ml
- Ti: 0.3-3 s

English / Español / Português / Deutsch / 中文（简体）/ Français / Polski / Italiana / Türk / Русский / Nederlands / Ελληνικά / 한국어 / Magyar / ไทย

H-80A High Flow Humidifier oxygen therapy

Therapeutic product for COVID-19 patients

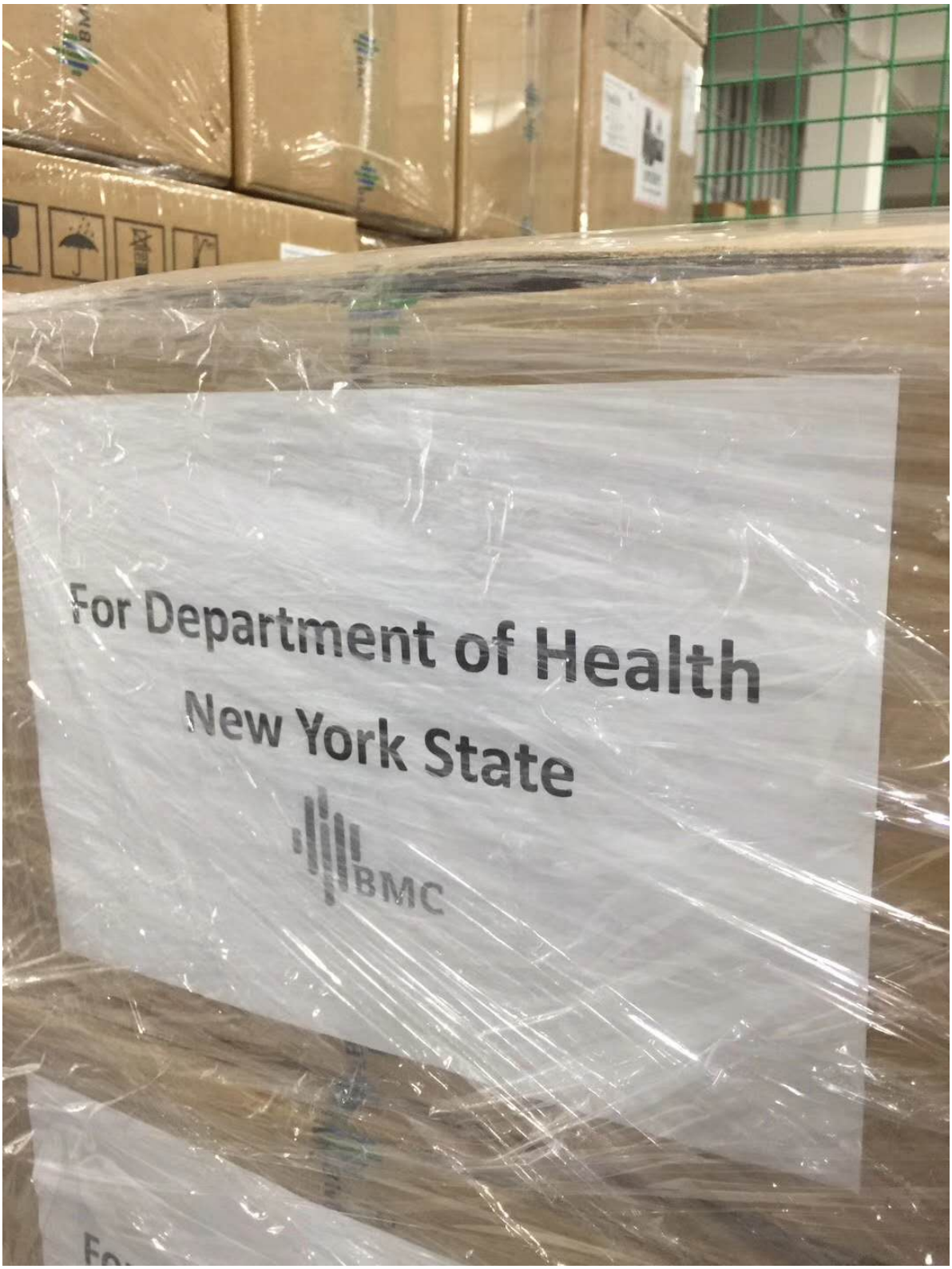
- Mode: HFlow / LFlow
- Adjustment Method of Oxygen Concentration: Auto
- Flow Rate: 2-80 L/min
- Temperature Output Range: 29-37℃
- Temperature Adjustment Gear: 9 steps adjustable
- Whether the host is disinfection-free: Yes
- Trend Review Function: 1 days; 3 days; 7 days
- Automatic filter replacement function: Yes, can be set
- Automatic water refill tips: Yes
- Humidity Compensation: -3~+3, 7 steps adjustable

- Hot standby function: continue heating while treatment was temporarily stopped, maintaining optimal temperature and humidity to restart
- Support O2 automaticly mixed at range of concentrations up to 100%
- Real-time monitoring: FIO2, Flow, temperature, Res rate

BMC Medical Co., Ltd. en.bmc-medical.com

Shipment to New York State Department of Health

April 2020



Shipment to Spain

March 2020

Shipment to European Union's Directorate-General for Health

March 2020