User Manuel

Non-Invasive Ventilator DMi520/525/530 Dear user

Thank you very much for using our non-invasive ventilator. I sincerely hope it can bring you health and happiness. If you have any comments and suggestions during the use, please contact us in time.

About this manual:

- Before using the setting and maintenance equipment, please read this manual carefully, so that you can understand how to operate correctly and make the treatment reach a better state.
- This manual covers the installation, use and daily maintenance of noninvasive ventilator (applicable model: DMi520 / 525 / 530).

Table of contents

| 1 | Warnings and Precautions | 1 |
|----|---|----|
| 2 | Safety and Responsibility | 1 |
| 3 | Introduction | 3 |
| 4 | Use guidance | 7 |
| 5 | Product functions and parameters | 9 |
| 6 | Preparation for use | 11 |
| 7 | Use | 12 |
| 8 | Alarm | 15 |
| 9 | Cleaning and Maintenance | 17 |
| 10 | Analysis and elimination of common problems | |
| 11 | Technical specifications | |
| 12 | Annex | 22 |
| 13 | Symbol meaning | 22 |
| 14 | EMC | 23 |
| 15 | Warranty | |

1 Warnings and Precautions



The product must be used in the following circumstances:

- Use the machine according to the instructions of the user manual and clinician.
- Use the machine according to the instructions of the user manual and clinician.
- Attachments designated or approved by Dawn Medical must be used.

Other circumstances may result in personal injury or equipment damage. The product should not be used in any form of life support therapy.



- Please read this manual carefully before using the ventilator, so that you can understand the operation specifications and maintenance requirements of the equipment more comprehensively, and set appropriate parameters according to your doctor's guidance, so that the treatment can be more effective
- Dawn medical has the right to change the product without notice.
- The schematic diagram and list of components are confidential. Please contact our customer service if you need.
- 2 Safety and Responsibility
- 2.1 How to use it safely
- 2.1.1 Precautions for ordinary users
- Switch it on and off at least once a week to make itself detect.
- When you change other treatment sites and medical personnel or will carry out other forms of treatment, please be sure to inform the relevant medical personnel that you are undergoing mechanical ventilation treatment.
- If the equipment is suspected of damage, there is pressure change for unknown reasons, equipment shaking, sound change, abnormal temperature rise of the casing, or the temperature of the conveying air flow is too high and has peculiar smell, please stop using and contact your nursing personnel to check the equipment.
- Improper use of accessories may cause invalid treatment or degradation of equipment performance.
- Only accessories designated or approved by dawn medical can be used.
- Before using the product, please refer to the content of "installation before use" in this manual. The user must carefully read this manual to understand the correct use of the product.

- The clinician should carefully read the clinician's manual before setting to understand the correct operation of the product.
- All physiological alarms of the product must be set at the safety level. Before setting, the relevant settings of the ventilator shall be considered, and the patient or user shall be informed to avoid any danger. The physiological alarm level must be reset for any change of settings or replacement of accessories.
- When the equipment is not used, please place or package the ventilator properly.
- If it is necessary to put the ventilator into the backpack, please do not use the ventilator, and please remove the humidifier, unplug the power cord and air outlet pipe.
- If the product is used for vehicle transportation or patient transfer in a short period of time, the following precautions shall be followed:
 - a) Do not install the product on wheelchair or vehicle.
 - b) Make sure that the product is firmly in an upright position and do not tilt or fall.
 - c) Do not use the product outdoors when it rains or snows.
 - d) Do not place the product in direct sunlight.
- 2.1.2 Power safety
- Before using the product, it is necessary to check the household electrical facilities (such as power socket) to ensure that they are well grounded, otherwise, do not use the product.
- If the outer layer of power supply or wire is damaged and there is possibility of leakage, please do not use the product.
- Please disconnect the power supply before cleaning the equipment, and do not wash the product in any liquid.
- When processing the humidifier heating device, please turn off the product and disconnect the power connector
- Close the product before disconnecting or connecting the humidifier water tank
- The performance of the product may be reduced under the following circumstances:
- AC supply voltage below 15% and above + 10% of declared nominal value

2.1.3 Environmental conditions

- Do not use the product in toxic or air polluted environment.
- It is not allowed to use the product in explosive or flammable environment.
- It can not be used in the case of mixture of flammable anesthetic gas and air or oxygen or nitrous oxide.
- It is not allowed to use the product in MR environment.
- If indoor humidifier is used, please place it 2 meters away from the product.
- When the environment and power supply exceed the limit of the following range, changing one of the parameters to keep other parameters in the normal range may reduce the product performance, but will not cause safety hazards.
 - a) Ambient temperature: 5 $^{\circ}$ C 40 $^{\circ}$ C;
 - b) Relative humidity 10% 95%;
 - c) Atmospheric pressure 700hPa 1060hpa;

- d) AC supply voltage 15% + 10% of rated voltage.
- It is not allowed to use the product in a warm place, such as under direct sunlight.
- During the use of the equipment, in order to meet the EMC requirements, the measures include but are not limited to:
 - a) Avoid using equipment with electromagnetic radiation within 1 meter of the product, such as:
 - b) Mobile phones, radio equipment, microwave ovens, etc.
 - c) Please pay attention to the relative humidity and conductivity of the clothes to avoid the accumulation of static electricity.
- The waste disposal of any accessories of the product shall comply with the environmental protection regulations of the local relevant departments on waste disposal.
- If the technical specifications specified in this manual are not met, the performance of the equipment may be degraded or the treatment of patients may be affected. Please do not use the product immediately after transportation or storage in addition to the recommended operating conditions. The product shall be placed in the specified working and operating environment for more than 2 hours before use.

2.2 Exemption from liability

The company will not bear the maintenance cost for the damage caused by the following reasons.

- Without the permission of the company,
- Personal unauthorized modification, function expansion and repair.
- Use accessories and accessories not recommended by the company or without registration certificate.

Do not use the treatment machine according to the manual

3 Introduction

3.1 overview

The non-invasive ventilator of our company is a kind of ventilator with pressure control and pressure support. It adopts positive pressure ventilation. The product is used for adult patients with weight over 30kg to treat obstructive sleep apnea syndrome.

DMi520 / 525 / 530 has two operation modes: S / T mode and CPAP (continuous positive airway pressure).

• S / T mode: pressure support / control mode

This mode can be triggered by autonomous respiration or by machine control. It is determined by the strength of the patient's autonomous respiration. It can adjust the inspiratory pressure (IPAP), end expiratory airway pressure (epap), respiratory rate (RR), inspiratory time (TI) and Inspiratory trigger sensitivity, etc.

• CPAP mode: continuous positive airway pressure ventilation mode

In this mode, keep the airway pressure unchanged, adjust the sensitivity of inspiratory and

expiratory triggering and CPAP.

The ventilator has a pressure sensor inside, which can continuously monitor the change of airway internal pressure and accurately collect the signal of patients triggering breathing.

3.2 Scope of application

- It is only applicable to patients with autonomous breathing.
- It is designed for noninvasive ventilation and is not suitable for invasive ventilation.
- It shall not be used for any form of life maintenance, life support, emergency rescue and transportation of critical patients.
- It can be used in hospitals, some medical institutions, rehabilitation institutions and families. It must be used in strict accordance with the guidance of clinicians and this operation manual.
- Suitable for adult patients (weight > 30 kg).
- Daily use time is up to 20 hours.

3.3 Contraindications

Do not use the ventilator in patients with severe respiratory failure who cannot breathe autonomously.

Stop using the ventilator when the following diseases or symptoms occur:

- Disease rational hypotension
- Serious arrhythmia
- Unstable angina
- Decompensated heart failure or hypotension, especially related to lack of blood volume
- Untreated pneumothorax
- Gas accumulation in mediastinum
- Serious epistaxis or history of serious epistaxis (risk of recurrence)
- Brain hernia, recent brain surgery injury or brain surgery (can lead to skull nasopharynx impotence)

Positive airway pressure should be used with caution in suspected patients, such as those with abnormal cribriform plate or a history of brain injury.

If the patient shows signs of sinusitis or otitis media, treatment may need to be temporarily disabled.

3.4 Adverse symptoms

If you feel discomfort or any of the following symptoms when using the product, please contact your doctor or clinical staff immediately:

- A large amount of gas inhaled when awake causes stomach distention
- Continuous air leakage at the mouth during sleep
- Dry airway and nose
- Ear pain, runny nose or sinus pain
- Daytime sleepiness
- Disorientation or memory loss

- Mood change or irritability
- Skin allergy

3.5 Product composition

3.5.1 Main composition

| Part name | Function description | Legend |
|--------------------------|-------------------------------|----------------|
| Product mainframe | Equipment main body | DMi520/525/530 |
| Product manual | Product information and usage | |
| Adapter | For external power supply | |
| Power cord | For external power supply | H. |
| Filter cotton (washable) | Filter air inlet | |

3.5.2 Panel



| SN | Name | function |
|----|--------------------------|---|
| 1 | Display | Display of set parameters, monitoring data and air pressure diagram |
| 2 | Trigger indicator | Light up when inspiratory air is detected |
| 3 | Standby switch button | Put the ventilator in standby mode or operation mode |
| 4 | Pipe interface | Interface to patient circuit or humidifier |
| 5 | Enter key | Determine settings |
| 6 | Down / down key | Move the cursor down or decrease the set parameter |
| 7 | Up / up key | Move the cursor up or add the set parameter |
| 8 | Menu key | Menu entry |
| 9 | Mute | Eliminate alarm sound, alarm light and alarm display |
| 10 | External power indicator | Power on often bright |
| 11 | Alarm indicator | On when the corresponding alarm is triggered |



| SN | Name | Function |
|----|--------------------------|---------------------------------------|
| 1 | Air inlet filter screen | Filter the gas entering the equipment |
| 2 | External power interface | Power line connection |
| 3 | USB interface | Export user data |
| 4 | TF card | Store user data |
| 5 | Humidifier liquid window | Check the water level of humidifier |

4 Use guidance

4.1 Use of patient circuit

- When using the product, please use the special mask with air leakage recommended by dawn medical or health care experts (it should meet the requirements of the industry standard YY 0671.2-2011 sleep apnea treatment part 2: mask and application accessories), patient circuit (it should meet the requirements of the industry standard YY 0461-2003 anesthesia machine and respirator breathing pipeline).
- The product needs a leak rather than an actively controlled exhalation valve to remove the gas in the patient's circuit. Therefore, a special mask with a leak and a patient's circuit need to be used. The continuous air pressure in the airway can make the gas exhaled by the patient discharged from the leak and prevent the possibility of

re inhalation. Before starting the product, the leak must be checked.

- It is not allowed to breathe in the patient's circuit unless the product has been started normally.
- It is not allowed to use the patient circuit made of electrostatic or conductive materials.
- The filter screen must be inspected and replaced regularly to ensure the normal operation of the product. The treatment of the replaced filter screen shall comply with the regulations of the local relevant departments on waste treatment.
- Regularly check whether there is moisture in the patient's circuit. If there is, it needs to be removed. When drying the circuit, first disconnect the circuit from the product to ensure that the water drops will not flow back into the product.
- If the patient needs help to remove the patient interface, it is not allowed to leave the patient alone, which is to avoid repeated inhalation of CO2 due to the failure of the ventilator.
- If a full face mask is used, the mask has an exhaust valve.
- Ensure that there is no blockage or foreign matter in the air leakage port, which is to discharge the gas exhaled by the patient. If the air leakage port is blocked, the patient will inhale CO2 repeatedly.
- When the pressure of CPAP is low, the pressure is not enough to discharge all gases, so there is the possibility of repeated inhalation of CO2 by patients.
- The hose on the hospital bed should not be too long. When the patient sleeps, it may wrap the neck around or press the hose when turning over to cause suffocation.
- The use of the mask always follows the instructions of the mask manufacturer.

4.2 Use of filter screen

- When using the product, it must be equipped with a patient air inlet filter, and only use the filter specified by dawn medical.
- Regularly check and replace the filter screen, especially when replacing patients, not cleaning the filter screen may increase the air intake resistance and make the product run beyond the predetermined temperature.
- When using the product, ensure that the air inlet and filter screen are not blocked.
- The use of high resistance bacterial filter screen at the air outlet may affect the function of the patient to disconnect the device, and may also affect the trigger function of the ventilator.

4.3 Use of oxygen

- Oxygen can make combustible materials burn faster.
- If you need to access oxygen, please connect the oxygen interface to the corresponding interface on the mask or the respiratory system circuit.
- Under the fixed flow rate of the supplementary oxygen flow, the oxygen concentration inhaled will be different, which mainly depends on the input pressure, patient's breathing mode, mask selection and leakage rate.
- When oxygen and product are used at the same time, if the product is closed, the

oxygen flow shall be closed first.

- If oxygen is used indoors, do not smoke.
- Maintain good indoor ventilation.
- The uncovered bulb and fire source must be at least 2m away from the oxygen source or any part of the patient circuit.
- Even if the oxygen source has been closed, aerosol and solvent cannot be used around it.
- If the product has been closed and the oxygen flow has not been closed, the oxygen input into the patient's circuit will accumulate in the ventilator, and the accumulated oxygen will be in danger of fire.
- The added oxygen may trigger the low air leakage alarm in advance.
- Make up oxygen flow shall not exceed 15 L / min.
- Supplement of oxygen will affect capacity accuracy and flow measurement.

4.4 Use of humidifier

- Before loading and unloading the water tank, be sure to turn off the ventilator.
- Prevent water from entering the ventilator. Make sure that the ventilator with the humidifier installed must be lower than the patient and placed on a flat surface. This is to prevent personal injury due to accidental spillage, or excessive or condensed water flowing into the patient's pipeline and mask.
- When the humidifier and ventilator are connected together, do not inject water or pour out water.
- Make sure all parts are dry before operation of ventilator. If water spills out after filling, dry with a lint free cloth and reconnect to the ventilator.
- In order to avoid scalding, when the humidifier is powered on or not cooled, pay attention not to contact the water in the water tank.

5 Product functions and parameters

5.1 Ventilation mode

The following breathing modes are available

| Breathing pattern | DMi520/DMi525/DMi530 |
|-------------------|---|
| S/T mode | Pressure support / control mode |
| CPAP mode | Continuous positive airway pressure ventilation |

- Under CPAP mode, the maximum pressure of the ventilator at the patient's connection port under normal condition shall not exceed 20 cmH2O, and under single fault condition shall not exceed 30 cmH2O.
- In other modes, the maximum pressure of the patient's connection port under normal state of the ventilator shall not exceed 30 cmH2O, and shall not exceed 40 cmH2O under single fault state.
- According to the test conditions specified in 56.103 of YY 0671.1-2009, the pressure change is less than 3cmH₂O.

| | | | | 1 / 3 of max pressure: | 90 L / min |
|-----------------|------|----|------|------------------------|-------------|
| Maximum mode | flow | in | CPAP | 2 / 3 of max pressure: | 120 L / min |
| | | | | Max pressure: | 145 L / min |

5.2 Set up

RAMP function

It is used to increase the IPAP pressure within a set period of time. The IPAP pressure starts from 2cmh2o higher than the delay boosting pressure.



In CPAP mode, the delay boosting function can increase the starting pressure of delay boosting to the set CPAP pressure within the set time period.

If your caregiver turns off this feature, it will not work

The low pressure alarm will be stopped within the time of delay boosting

5.3 Standby and operation mode

Standby mode is defined as the state when the main power supply is turned on and the display is on, but the product is not started.

The operation mode is defined as the state when the fan has been running and generating air flow.

To start the product in the standby mode, press and hold the standby switch key for more than 1 second to enter the operation mode interface, return to the standby mode in the operation mode and press the standby switch key for more than 1 second to enter the standby mode interface.

5.4 Low air leakage detection

The product can check whether there is enough air leakage in the mask and breathing pipe by itself. The test data is displayed on the display screen, during which the product continues to provide breathing.

Check face mask, air leakage / exhalation port and breathing pipe, and clean blocked vent if necessary.

5.5 Water injection of humidifier

- Fill the water tank with distilled water only, or tap water cooled after boiling. This is to reduce mineral precipitation and extend the maximum life of the tank.
- Do not add hot water to the tank.
- Do not overfill the water tank. The water tank can only be filled to the marked maximum level.
- Always make sure that the tank top cover and gasket are properly connected after filling or reassembling the tank. Also check that the water tank is correctly positioned and secured to the heater.
- Avoid removing the gasket from the top cover of the water tank during daily normal use.
- Make sure that all components are dry before the ventilator is powered on.
- Follow the steps below to fill the humidifier. Follow the same procedure when pouring water out of the tank.
 - \diamond Close the ventilator.
 - ♦ Open the side plate and take out the water tank from the main engine.
 - Break off the sealing bayonet of the water tank, open the water tank to inject water into the water tank, and the water level shall not exceed the maximum water level of the water tank.
 - ♦ Connect the top cover of the water tank with the water tank to ensure correct assembly, push the water tank into the main engine and close the side plate.

When the humidifier and ventilator are connected together, do not inject water

6 Preparation for use

2 Please refer to "safety tips" before setting up and using the product.

6.1 Installation

For first use, follow these guidelines:

- Check that all main parts and ordered accessories have been delivered.
- Confirm that the equipment is in good condition
- Check whether the air filter screen has been installed.

6.2 Place

Please refer to "environmental conditions" carefully to ensure that all conditions have been fulfilled and considered.

- Place the product on a stable plane and face the patient.
- The product should be placed lower than the patient to avoid the equipment falling and hurting the patient, and prevent condensate from reaching the patient.
- Ensure that there is no object blocking the patient air inlet behind the product.
- 6.3 Connect the product to the main power supply

Please refer to "electricity safety" carefully to ensure all conditions have been fulfilled and considered.

Connect the product to the main power supply

- Insert the output end of the adapter into the external power interface of the product.
- Connect the power cord to the adapter, and then connect the power cord to the power socket.

6.4 Connect patient loop

Please refer to "use of patient circuit" carefully to ensure all conditions have been fulfilled and considered.

Noninvasive ventilation

- Connect the patient circuit with the air outlet.
- Connect the other end of the patient circuit to the mask and the air leak (if any).

Intentional leak

In order to prevent repeated inhalation of the exhaled gas from the patient, an air leakage port should be added in the patient circuit. At 4cmh2o, the air leakage volume of the mask or the air leakage port should be at least 12 L / min. It is recommended that the air leakage of the mask or the air leakage port is 20-40 L / min at the pressure of 10cmh2o.

Air leakage can be achieved by:

- The mask is equipped with integrated air leakage port
- Air leakage port connected

7 Use

7.1 Install products before use

The following steps must be carried out to use the product:

- Connect the clean or new patient circuit to the product.
- Connect the main power supply to the product and enter the standby interface (the power switch needs to be turned on for dmi530)
- Press and hold the standby key for more than 1 second to enter the operation interface, and the fan will rotate and generate flow. If the fan does not turn, stop using the product and contact your service provider.
- Make sure to adjust the ventilator settings according to the doctor's instructions.

2. Opening and Closing

- Start up: Make sure that the power cord is connected. After connecting the power, directly enter the standby interface
- Enter operation mode: Press and hold the standby switch key for more than 1 second to enter the operation mode interface to start the product.
- Return to standby mode: Press and hold the standby switch key for more than 1 second to enter the standby mode interface
- Close down: After entering the standby mode interface, unplug the power cord.

The product has the function of setting and alarm parameter memory. When the machine is restarted after normal shutdown or power loss shutdown, the setting and alarm parameter state before the last shutdown will be maintained for operation. Unless "restore factory setting" is selected, it will be changed to factory setting for operation.

7.3 Use of menus

Use the menu key on the front panel to enter the menu interface, and use the up / increase key, down / decrease key and enter key to realize browsing and parameter setting.

For the exact location of the buttons, see "Panel.".

On the required options, press enter to set the parameters, and then press enter to confirm.

During operation, if no key is pressed for more than 30 seconds, the menu will automatically switch to the main interface.

Symbols used in menus

| Symbol | Explain | | |
|--------|-------------|--------|-------|
| | RAMP Enable | Menu — | Enter |
| | | UP/ | Down |

7.3.1 Overview

The menu interface of the product is planned as follows:

1) Standby mode main interface

| Alarm | inform | ation | | |
|-------|--------|--------|------|--|
| | Mode: | ST | | |
| | IPAP: | 12 | | |
| D | EPAP: | 5 | | |
| | Tinsp: | 1.5 | | |
| A | | | | |
| w | Do | own | Quit | |
| N | | Alarm | | |
| | | Others | | |

The interface displayed when the product is in standby mode, in this state, the fan is in the

stop state, and the product can be set up.

2) Main interface of operation mode

The product fan has been started and generates air flow. This interface can set the relevant parameters of the product. The air pressure value of the selected mode will be displayed on the left side and the monitoring parameters will be displayed on the lower side.

| Alarm | Informa | ation | | | | |
|------------------|-----------------------------------|----------------------|-----|-----|-------|----|
| P r e s | Mode: IPAP: EPAP: Tinsp: | ST 12 5 1.5 | | | | |
| s | De | own | 5 | | Quit | |
| | Rate 15 | | bpm | I:E | 1:2.0 | |
| | Leak 15 | L/MIN | | VT | 300 | ml |

3) Information bar

The information bar displays time, tfcard, alarm clock, delay boost, humidifier and other information.

4) Respiratory parameter setting

Press the menu key, and a gray light bar will appear at the "breathing mode" to enter the breathing parameter setting state. Press the down / down key to make the gray light bar to the parameter to be set, press the Enter key, the corresponding value will be illuminated, and change the value of the parameter to be set through the down / down or up / up key, and press the Enter key to confirm.

For example, to set CPAP pressure to 20 cmH2O:

Press the menu key, press the down / down key to move the gray cursor to the "CPAP pressure", press the Enter key, the "CPAP pressure" value will be on, press the up / up key to adjust the value to 20 cmH2O, and press the Enter key.



5) Alarm and other parameter settings

In the main interface, move the cursor to the "down" menu and press to enter the selection area of other parameters and alarm parameter settings.

| Alarm | inform | ation | | |
|-------|--------|--------|------|--|
| | Mode: | ST | | |
| | IPAP: | 12 | | |
| D | EPAP: | 5 | | |
| | Tinsp: | 1.5 | | |
| A | | | | |
| w | C |)own | Quit | |
| N | | Alarm | | |
| | ľ | Others | | |
| | | | | |

8 Alarm

Whenever the setting of the product is changed, the setting of the upper and lower limit of the adjustable alarm should be reevaluated.

The operator shall be at the position in front of the ventilator where the visual alarm signal and the auditory alarm signal can be accurately (clearly) detected. There is a certain risk in the limit setting of the upper and lower limit of alarm parameters. Please set it correctly according to the guidance of the clinician.

8.1 Alarm function

The alarm function of the product consists of the LED alarm light on the front panel, the alarm tone and the information on the display screen.

8.1.1 Alarm indication

When starting, check whether the alarm sound level is set to the appropriate volume according to the ambient noise level.

When the alarm condition is met, the alarm is displayed in three ways:

- LED lights on the front panel :
 - Red indicator on the lower side: high priority, flashing twice per second.
 - Upper yellow indicator: medium priority, flashing every two seconds.
- Alarm information on the display screen: display the name of the alarm situation (!!! High priority alarm!! Medium priority alarm). When multiple alarms occur at the same time, the rolling display mode will be used to alternately display all alarm information.
- Alarm tone: indicates the priority level of the alarm situation.
 - high priority: 3, then 2, stop for 1 second, then 3, then 2, stop for 5 seconds, 10 for one cycle. The high priority alarm sound pressure range is 55dB (a) ~ 75db (a).

- Medium priority: only 3 times, stop for 5 seconds and repeat. The medium priority alarm sound pressure range is 50dB (a) ~ 70dB (a).

8.1.2 Alarm tone pause and reactivate

Press the mute key to pause the alarm tone. If the ventilator recognizes that the same alarm condition still exists after the mute period, the alarm tone will be reactivated. The mute time is no more than 120 seconds.

If a new alarm condition occurs during mute, the alarm tone will be reactivated. To ensure that any new alarm situation is detected in time, do not leave the patient unattended when the alarm is suspended.

8.1.3 Alarm reset

Once the cause of the alarm has been corrected, press the mute button to clear the corresponding alarm message.

If the alarm cannot be corrected, stop using and repair the product.

8.1.4 Power failure alarm

Alarm shall be given immediately after power failure.

8.2 Physiological alarm

8.2.1 Low pressure alarm

| Project | Explain | |
|------------------|--|--|
| Definition | If the pressure of the product fails to reach the low-pressure alarm | |
| | limit for 15 seconds, a low-pressure alarm will be given. | |
| | The patient circuit is disconnected | |
| Possible reasons | The setting parameters are too high | |
| | Leakage of mask or other parts of patient circuit | |
| User detection | Pomovo the mask during normal operation | |
| mode | Remove the mask during normal operation. | |
| Ventilator | The product will continue to provide breathing with the same settings | |
| response | The product will continue to provide breathing with the same settings. | |
| Instructions | A medium priority alarm tone is emitted, and the upper yellow alarm | |
| | light flashes and messages. | |



The low-pressure alarm will be stopped in RAMP.

8.2.2 High voltage alarm

| Project | Explain | | |
|--|---|--|--|
| Definition If the pressure in the circuit is more than 5cmh2o than IPAP, | | | |
| | breathing machine will give a high pressure alarm. | | |
| Possible reasons | Occurs only under abnormal conditions, such as severe coughing in | | |
| | the respiratory phase. | | |
| User detection | When working normally and in the inspiratory phase, block the air | | |
| mode | leakage port and exhale forcefully in the mask. | | |

| Ventilator response | In case of high pressure alarm, the product will end inspiratory and automatically switch to expiratory state. The product will continue to provide breathing with the same settings. |
|------------------------|---|
| Instructions | Send out the high priority alarm sound, and the red alarm light on the lower side flashes and information |
| | lower side hashes and information. |

9 Cleaning and Maintenance

9.1 Cleaning

In order to avoid electric shock, the main power supply must be disconnected from the product. Do not immerse the product in any liquid.

- The product shall be cleaned and maintained according to this manual.
- please be careful when cleaning products to avoid damaging any parts.
- Do not let liquid flow into the product.
- It is not allowed to sterilize the product under high pressure.
- Do not immerse the product in any liquid for cleaning.
- Use a lint free cloth with alcohol to wipe the surface of the product host.

9.1.1 Turn off

- Close the product and disconnect the main power supply.
- Remove the patient circuit.
- Disconnect all power supplies.
- Clean the product surface with lint free cloth and neutral soap solution.
- Reconnect the patient circuit. Make sure all parts are dry before using the product.

9.1.2 Patient circuit (pipeline, humidifier and mask)

- Please clean, disinfect and replace the patient circuit as directed by your caregiver.
- When new patients use the product, be sure to replace the new patient circuit.
- All parts in contact with breathing air must be cleaned.
- The time of using the patient's circuit shall not exceed 90 days.

If using the patient loop components recommended by dawn medical, clean them up as follows:

- Soak the removed parts in hot water with neutral detergent.
- Clean the dirt with a brush.
- Wash the parts thoroughly with hot water.
- Dry the water in the parts.
- Dry the parts thoroughly.
- Store in a dry and ventilated environment.

Check the patient circuit regularly for damage. If damaged, replace the circuit.

9.1.3. Clean and replace the patient air filter screen

- The patient air filter screen is located at the rear end of the ventilator.
- Washable filter screen (gray)

- The washable filter screen shall be replaced at least once a year. Wash at least once a week.
 - Clean the filter screen with warm water and neutral soap solution.
 - Wash thoroughly.
 - Use a towel to squeeze out the water in the filter screen. Do not twist the screen.

9.2 Regular maintenance management

Regular maintenance inspection and management shall be carried out at least every 12 months.

Stop using the device and contact your caregiver to check the device if:

- During the treatment, the patient has unexpected symptoms.
- During operation, there are unknown or sudden pressure, performance or sound changes.
- Suspected damage of equipment.

9.3 Deposit

Clean, clean and dry the machine before storage.

9.4 Waste disposal

All accessories and replacement parts must be in accordance with the local relevant old equipment and waste



Dispose of or reuse in accordance with environmental regulations.

10 Analysis and elimination of common problems

1. Finding and eliminating problems

| problem | Possible reasons | Possible cause solution | |
|---|---|--|--|
| | The mask is not worn properly | Re wear the pipe | |
| | Pipe shedding | Reconnect the pipe | |
| Mask fall off | Internal leakage | Contact a caregiver or service person | |
| | Humidification cup not assembled in place | Reinstall the humidification cup | |
| Severe dry mouth after use | Humidifier not used | Turn on the humidifier | |
| | Humidifier gear too low | Increase humidifier gear | |
| Too much condensate in the pipeline after use | Humidifier gear high | Decrease humidifier gear | |
| | The temperature difference inside and outside the pipeline is too large | Turn on the indoor air conditioner or use the heating pipe | |
| Fan fault | Internal problems of the machine | Contact a caregiver or service person | |

| Humidifier does not | No electricity | Check the power cord of the ventilator Check the connection of the power port at the back of the ventilator |
|---------------------------------|---|--|
| work | Humidifier water temperature too high | Contact a caregiver or service person |
| | Heating element is damaged | Contact a caregiver or service person |
| | Tank overflowing | Check the liquid level and pour out excess water if necessary |
| water tank is leaking | The top cover of water tank is not placed correctly | Check the top cover and gasket of water tank |
| | Damaged or damaged water tank | Contact the caregiver or service person for replacement. |
| Water seeps into the | Humidifier gear set too high | Lower humidifier set gear |
| patient's pipeline | Tank overflowing | Check the liquid level and do not pour out excess water |
| The patient inhales too wet air | Humidifier gear set too high | Lower humidifier set gear |
| | Tank overflowing | |
| The patient does not | Humidifier gear set too low | Increase the setting gear of humidifier |
| inhaled | | Contact a caregiver or service person |

10.2 Repair

Carry out maintenance management according to the product maintenance manual.

- It is necessary to maintain, repair, manage and upgrade the product according to dawn medical's maintenance instructions.
- only authorized maintenance technicians who have received maintenance training of dawn medical products or maintenance technicians with the same technical knowledge of medical equipment can repair and update the products according to dawn medical maintenance manual, technical bulletin and any special maintenance guide.
- In any case, it is not allowed to repair the product by itself. Otherwise, the manufacturer is no longer responsible for the performance and safety of the product, and the warranty will automatically expire
- Failure to follow these maintenance instructions may result in personal injury!
- The service and maintenance of the product shall be carried out by authorized maintenance personnel in accordance with the dawn medical maintenance guide. Always perform service checks after any repair of the equipment.
- Authorized repairers can order product maintenance manual, which contains all necessary technical data for maintenance and repair of products.

11 Technical specifications

11.1 Data

Its packaging does not contain any natural rubber ingredients.

| Setting / | Range /Performance | Adjustmen | Factory |
|--------------------------------------|--|----------------------|-----------------------|
| Value | | t range | settings |
| Ventilation | S/T Mote (Pressure Support/Control Ventilation) CPAP Mote (Continuous Positive Airway Pressure) | | |
| IPAP | $4\sim$ 20cmH2O; \pm 10% or \pm 2 cmH2O | 1 cmH ₂ O | 12 cmH ₂ O |
| CPAP | 4~20cmH2O; ±2 cmH2O | 1 cmH ₂ O | 12 cmH₂O |
| EPAP | 2~20cmH2O; ±2 cmH2O | 1 cmH₂O | 4 cmH ₂ O |
| Breath Rate | $4{\sim}60$ BPM , ±1BPM or ±10% | 1 BPM | 10BPM |
| Inspiration time | 0.3~5s; ±0.1s or ±10% | 0.1s | 1s |
| Pamp time | $10{\sim}60$ min, off ±1min | 10min | off |
| The following applies to DMi530 only | | | |
| inspiratory flows | 1-5 | 1 | 3 |
| Inspiratory triggering | 1-5,关 | 1 | 3 |
| Expiratory triggering | 1-5 | 1 | 3 |

| Alarm | Range | Indication | Factory settings |
|--------------------------------------|--|--|---------------------|
| Low pressure alarm | $2-20$ cmH ₂ O; ± 2 cmH ₂ O; Adjustment range 1 cmH ₂ O | Upper yellow LED warning light, alarm tone and display warning information | 6 cmH₂O |
| High voltage alarm | Is a fixedvalue: IPAP+5cmH ₂ O ; :±2 cmH ₂ O; | Red LED warning light, alarm tone and display warning information on the lower side | |
| The following applies to DMi530 only | | | |
| Low respiratory rate alarm | 4-30BPM; ±1BP or ±10%, The greater of the two. ; adjustment range 1BPM | Upper yellow LED warning light, alarm tone and display warning information | 6BPM |
| High respiratory | 10-60BPM ; ±1BPM or±10%, The greater of the | Upper yellow LED warning light, alarm tone and | 40BPM |

| rate alarm | two. ; adjustment range 1BPM | display warning information | |
|----------------------------------|---|--|----|
| Low air leakage alarm | On / off | Upper yellow LED warning light, alarm tone and display warning information | On |
| High air leakage alarm | On / off | Upper yellow LED warning light, alarm tone and display warning information | On |
| Internal battery low alarm | Internal battery lower than 22.5 ± 0.2V | Upper yellow LED warning light, alarm tone and display warning information | |
| Internal battery low alarm | Internal battery lower than 21.5±0.2V | Red LED warning light, alarm tone and display warning information on the lower side | |

| Monitor | Range | Tolerance |
|-------------|---|---|
| pressure | 0∼40cmH₂O | \pm 2 cmH ₂ O or \pm 10%, whichever is greater |
| Breath Rate | 4~60 BPM | ± 1bpm or ± 10%, whichever is greater |
| I:E | 1:0.5~1:10 | ±15% |
| Leakage | 0~100 L/min; show"100+ "when leakage above 100L/min | ± 20% or ± 10 L / min, whichever is greater |

| performance index | Bata | |
|--|--|--|
| Working noise | It shall not be greater than 35dB (a) when operating at 10cmh2o pressure | |
| Maximum pressure at the patient | | |
| connection in a single fault condition | Not more than 40 cmH ₂ O | |

| Power Supply | Specifications |
|-------------------------------|----------------|
| Main power supply | AC 220V, 50Hz |
| Fuse | F3.15A L250V |
| Input power | 1.8A |
| Internal battery (for DMi530) | 2.3AH, DC 24V |

| Classification of | Class I internal power supply (DMi530 only) |
|-------------------|---|
| safety protection | Type B application part of common equipment |

| | It can not be used in the mixture of flammable anesthetic gas and air | |
|----------------|---|--|
| | or oxygen or nitrous oxide | |
| Equipment | Continuous operation | |
| operation mode | | |

| project | Operating | Environmental | Storage/Transport |
|-------------------|-----------------------|---------------|-------------------|
| project | Conditions | | Environmental |
| Ambient | 5~40℃ | | -20∼55℃ |
| temperature | | | |
| Atmospheric | 700 \sim 1060mbar | | |
| pressure | | | |
| Relative humidity | 10 \sim 95%,Non-con | densing | Above 93% |

12 Annex

| Name | Number |
|------------------------------|--------|
| DMi5 Non-Invasive Ventilator | 1 |
| User Manual | 1 |
| Certification | 1 |
| Breathing Hose | 1 |
| Mask (optional) | 1 |
| Nose mask (optional) | 1 |
| Filter | 1 |
| Power Cable | 1 |
| Adapter | 1 |

13 Symbol meaning

| Icon | Explain |
|---------------|--|
| ĺĺĺ | Refer to instructions for us |
| | Warning / Caution! Refer to attached documents |
| \rightarrow | Gas output |
| × | Type B application part |
| IPX0 | Waterproof protection level |

| | Production date (see label for details) |
|----------|---|
| Ţ | Fear of rain |
| × | Be afraid of drying |
| | Fragile |
| <u> </u> | Upward |
| 6 | Stacking layer limit: 6 layers |
| ×∎ | No rollover |
| X | Waste disposal of electronic and electronic equipment |
| ((·••))) | Interference may occur near equipment marked with the following symbols |

14 .EMC

This product complies with the requirements of GB 9706.1-2007 / yy0505-2012 for electromagnetic compatibility of products. Use and operation shall be in accordance with the following guidelines and manufacturer's declaration

- The use of ventilator shall be far away from fixed transmitter (such as ground radio base station, etc.).
- The ventilator is suitable for use in all facilities, including household facilities and the public low-voltage power supply network directly connected to the household residence.
- During the use of ventilator, in order to meet the EMC requirements, the measures include but are not limited to:
- a) Avoid using equipment with electromagnetic radiation within 1 meter of the ventilator, such as: Mobile phones, radio equipment, microwave ovens, etc.
- b) Please pay attention to the relative humidity and conductivity of clothes to avoid the accumulation of static electricity.
- Before using the ventilator, it is necessary to check the household electrical facilities (such as the power socket) to ensure that they are well grounded. Otherwise, do not

use the AC power supply, and use the ventilator powered by the internal battery instead.

- The ventilator shall not be used close to or stacked with other equipment. If it must be used close to or stacked, it shall be observed and verified that it can operate normally in its used configuration. In addition to the accessories and cables sold by the manufacturer of the equipment or system as the spare parts of internal components, the use of accessories and cables other than those specified may lead to the increase of emission (equipment or system) or the reduction of immunity.
- The ventilator only uses RF energy for its internal function, so its RF emission is very low, and the possibility of interference to nearby electronic equipment is very small.

| Guidance and manufacturer's statement electromagnetic emission | | | | | |
|---|-----------------|---|--|--|--|
| The ventilator is expected to be used in the electromagnetic environment specified below, | | | | | |
| and the buyer or user shall guarantee that it is used | in this elec | tromagnetic environment | | | |
| Launching test | Conform ance | Electromagnetic environment - Guidelines | | | |
| RF emission GB 4824 | 1set | The ventilator only uses RF energy for its internal functions, so its RF emission is very low, and the possibility of interference to the nearby electronic equipment is very small. | | | |
| RF emission GB 4824 | В | The ventilator is suitable for use in all facilities, | | | |
| Harmonic emission GB 17625.1 | A | including household and residential public | | | |
| Voltage fluctuation / flicker emission GB 17625.2 | 符合 | supply network directly connected to the household. | | | |

Form 1

Form 2

| Guidance and manufacturer's declaration - Electromagnetic Immunity | | | | |
|---|-------------------------------|------------------------|-----------------------|--|
| The ventilator is expected to be used in the electromagnetic environment specified below, | | | | |
| and the buyer sh | all ensure that it is used in | such electromagnetic e | nvironment | |
| Anti-interferenc | | | Electromagnetic | |
| е | IEC 60601 test level | Coincidence level | environment - | |
| measurement | | | Guidelines | |
| alastrastatia | ± 6kV contact | ± 6kV contact | The floor shall be of | |
| discharge CR/T | discharge | discharge | wood, concrete or | |
| | | | ceramic tiles and, if | |
| 17020.2 | ± 8Kv contact | ± 8Kv contact | covered with | |

| | discharge | discharge | synthetic material, | |
|---|-----------------------|-----------------------|-------------------------|--|
| | | | shall have a relative | |
| | | | humidity of at least | |
| | | | 30% | |
| Electrical fast | | | The network power | |
| | | | supply should have | |
| | ± 2 kV to power line | ± 2 kV to power line | the quality used in the | |
| 17626 / | | | typical commercial or | |
| 17020.4 | | | hospital environment | |
| | | | The network power | |
| surge GB/T | ± 1 kV line to line | ± 1 kV line to line | supply should have | |
| 17626 5 | | | the quality used in the | |
| 17020.0 | ± 2 kV line to line | ± 2 kV line to line | typical commercial or | |
| | | | hospital environment | |
| | < 5% UT for 0.5 weeks | < 5% UT for 0.5 | | |
| | (on UT. > 95% of sag) | weeks (on UT, > 95% | | |
| Power input | Power input | of sag) | The network power | |
| lineVoltage sag | On 40% UT for 5 | | supply should have | |
| Short time | weeks | On 40% UT for 5 | the quality of typical | |
| interruption | (60% sag on UT) | weeks (60% sag on | commercial or | |
| and voltage | | UT) | hospital environment. | |
| change | On 70% UT for 25 | | | |
| GB/T 17626.11 | weeks | On 70% UT for 25 | | |
| | < 5% UT for 0.5s | weeks< 5% UT for | | |
| | (on UT, > 95% of sag) | 0.55 | | |
| | | (on UI, > 95% of sag) | | |
| Power | | | Interference can | |
| frequency magnetic field | | | occur near equipment | |
| | | | | |
| | 3A/m | 3A/m | tollowing symbols: | |
| (50 Hz) | | | 7 | |
| | | | $(((\bullet)))$ | |
| GB/T 17626.8 | | | | |
| Note: UT refers to the AC grid voltage before applying the test voltage | | | | |

| Form | 3 |
|------|---|
| | - |

| Guidance and manufacturer's declaration - Electromagnetic Immunity | | | | |
|---|----------------|-----------|-------------------------------|--|
| The ventilator is expected to be used in the electromagnetic environment specified below, | | | | |
| and the buyer shall ensure that it is used in such electromagnetic environment | | | | |
| Anti-interfer | | | | |
| ence | IEC 60601 test | Coincide | Electromagnetic environment - | |
| measureme | level | nce level | Guidelines | |
| nt | | | | |

Note 1: on the frequency of 80 MHz and 800 MHz, the higher frequency band formula shall be adopted.

Note 2: these guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection of buildings, objects and human body.

Form 4

| Recommended is | olation | distance | between | portable | and | mobile | RF | communication |
|---|--|-----------------|----------|-----------------|--------|---------|-----|---------------|
| equipment and ven | tilator | | | | | | | |
| The ventilator is ex | The ventilator is expected to be used in an electromagnetic environment controlled by RF | | | | | | | |
| radiation disturban | nce. Ac | cording to | o the ma | ximum inj | put po | ower of | the | communication |
| equipment, the buyer or user of the ventilator | | | | | | | | |
| Electromagnetic interference can be prevented by maintaining the minimum distance | | | | | | | | |
| between portable and mobile RF communication equipment (transmitter) and ventilator | | | | | | | | |
| recommended below | | | | | | | | |
| Transmitter | 150 |) kHz \sim 80 | MHz 8 | 0 MHz \sim 80 | 00 MH | z 800 | MHz | ~2.5 GHz |

| maximum rating | (except for the band of engineering and medicine) | d = 1.2 \sqrt{P} | d = 2.3 \sqrt{P} |
|----------------|---|--------------------|--------------------|
| | d= 1.2 \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 |

15 Warranty

Under normal use, the warranty period of our company for this product and its accessories is as follows:

| product | Warranty time |
|------------------------------|---------------|
| DMi5 Non-Invasive Ventilator | 2 years |

The warranty period of this product is only for the first time purchased customers, and shall not be transferred.

The warranty of this product does not cover the following situations:

- Any problems caused by misuse, disassembly and transformation;
- It is carried out and maintained by a company not authorized by our company;
- Any damage caused by splashing water on the surface or inside of the electronic device.

All accessories and replacement parts of the product must be treated or reused according to the local environmental protection regulations on the treatment of old equipment and waste.

Registered person / manufacturer: Dawn Medical Instruments Shanghai Co., Ltd Address / production address: Room 1203-1206, 2nd floor, Building 10, No.185 Chexin Road, Songjiang District, Shanghai, China Production date: See product label for details Revision date: May 2019 Version No.: JS-04-01.V01