DECK MOUNT

ISO 80601-2-12
IEC 60601-1-1
IEC 60601-1-2

respirare

breathe easy

Bi-PAP with VAPS

BREATHING ASSISTANCE DEVICE

USER MANUAL

TABLE OF CONTENTS

1 INTRODUCTION

1.1 KNOW YOUR DEVICE

Respirare Bi-PAP is intended to provide ventilation for non-dependent, spontaneously breathing adult & pediatric patient (13 kg and above) with respiratory insufficiency with or without obstructive sleep apnea. The device is meant for non-invasive use in stationary mode — hospitals or home or mobile mode — wheelchair, ambulance etc.

Read the entire manual before using this breathing assistance device

1.2 INSIDE THE BOX


MASK


VENTED TUBE


CHARGER

Respirare may include the following components. Depending upon the model, some components or accessories may not be a part of your device package

1.3 CONTRADICTION

Respirare is not a life support device. If you have any of the following conditions, consult your doctor before using this device:

- Pneumothorax or Pneumomediastinum
- Pathologically low blood pressure, particularly if associated with intra-vascular volume depletion
- Cerebrospinal fluid leak, recent cranial surgery or trauma
- Severe bullous lung disease
- Dehydration.
- The use of the Respirare is contraindicated in an MRI environment and Invasive use.

1.4 CAUTION

You should report unusual chest pain, severe headache or increased breathless to your physician. The following side effects may arise during the course of non-invasive ventilation with the device:

- Drying of nose, mouth or throat
- Nosebleed
- Bloating
- Ear or sinus discomfort
- Eye irritation
- Skin rashes
- Gastric distension (Aerophobia)

2 SYSTEM OVERVIEW

2.1 FEATURES

Respirare Bi-PAP is a non-invasive ventilation device which augments patient breathing by supplying pressurized air through a breathing circuit. It senses the patient's breathing behaviour by monitoring airflow in the breathing circuit and adjusts its output to assist in inhalation and exhalation. This therapy is known as Bi-level Ventilation. Bi-level intimation provides a higher pressure, known as IPAP (Inspiratory Positive Airway Pressure), when you inhale, and a lower pressure, known as EPAP (Expiratory Positive Airway Pressure), when you exhale. The higher pressure makes it easier for you to inhale, and the lower pressure makes it easier for you to exhale.

Though these are the part of the devices only but, we have to fit two components to the device to make it functional -

- Patient Tube
- Full face mask (Non-vented) (a Vented mask should be used if there is no other leak port in the breathing circuit)

The following table illustrates some of the device connectors and features as described in the table below:

	Feature	Description
	Air Outlet Port	Connect the Vented tube here.
	DC Power Socket	Connect the power cord here. 12V/5Amp.
	Mask	Mask needs to be placed on the face of the patient in such a way that it covers the nose of the patient.
	Front veiw Air Filter Back veiw	The reusable filter screens out normal household dust and pollens.
	Humidifier	This machine comes with a detachable Humidifier. By warming and moistening the air you're breathing, humidification reduces dry nose and throat using a humidifier can improve comfort.

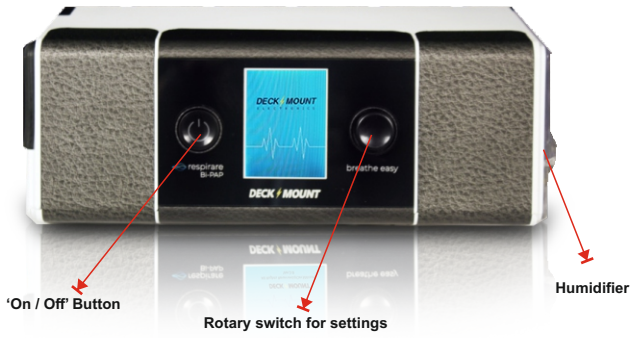
2.2 FRONT VIEW

Front face of the Bi-PAP has two buttons (as shown in the picture).

1.The First button (on the left side) is meant for starting the Bi-PAP Machine.

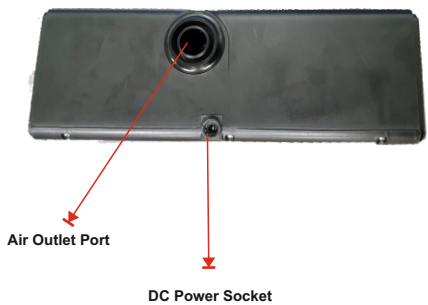
2.Second button (on the right side) is a rotary switch for operating the settings of the machine.

FRONT VIEW



1. At the rear of the Bi-PAP there is one Air Outlet Port which is to be connected to the Vented Tube for completing the breathing circuit.
2. Below the Air outlet port, there is a DC Power socket which needs to be connected to the Power connector of the adaptor provided with the machine

REAR VIEW



3 DEVICE SETUP

3.1 DEVICE BREATHING CIRCUIT

This device comes with a ‘Breathing Circuit’ containing Face Mask & Vented Tube. These individual parts need to be connected together to construct the breathing circuit.

1

MASK

2

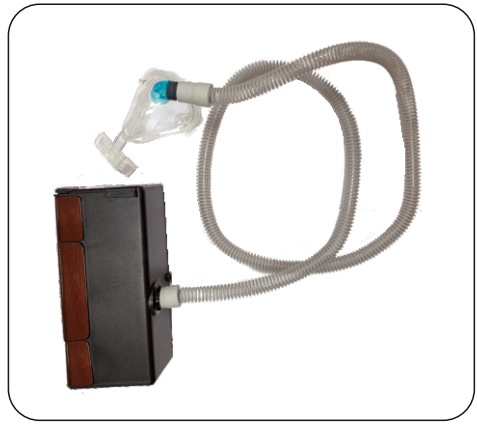
VENTED TUBE

Step -1: Connect one side of the Vented tube with the face mask. As shown in the picture below -

3

FACE MASK WITH TUBE

STEP-2: Connect the other side of the Vented tube to the Air outlet port located at the rear of the device. After connecting the tube, the final arrangement should look like as shown in the picture below.



With this, breathing circuit arrangement is complete.

3.2 POSITION THE DEVICE

Place the Device on a flat level surface Do not operate the Device while on its side, upside-down, or in any other orientation. Make sure that the air inlet on the back of the device is not blocked. If you block the air flow around the device, the Device may not work properly.

3.3 INSTALL THE AIR FILTER

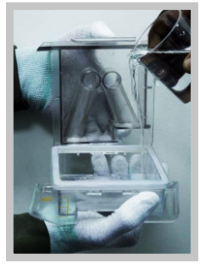
The device uses a washable foam filter (supplied with the device) at the device air inlet. The reusable filter screens out normal household dust and pollens. The filter must be in place at all times when the device is operating.If the filter is not already installed when you receive the device, you must install the filter before using the Device. Install the filter as shown below.

3.4 HOW TO USE HUMIDIFIER

1.Gently pull out the Humidifier as shown below

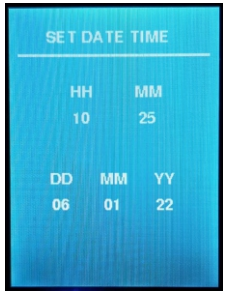
2.Open the Humidifier pulling the latch as shown below

3.Fill RO / Purified water in the Humidifier upto Maximum Level indicator & Replace in reverse order



3.5 HOW TO SET DATE AND TIME

Home Screen >> My Options >> Time set
Switch on the machine by pressing the power button . Set the Date & Time by Selecting the desired Parameters by navigating the options through Rotary switch.



4 THERAPY MODES AND FEATURES

4.1 THERAPY MODES

The device provides Pressure Control Ventilation (PCV) for non-invasive therapy. Pressure Control ventilation delivers a prescribed pressure to the patient according to set breath rate and set inspiration time parameters. This means that each breath is controlled so that a prescribed amount of pressure is delivered to the patient. The device offers four different Pressure Control modes of operation:

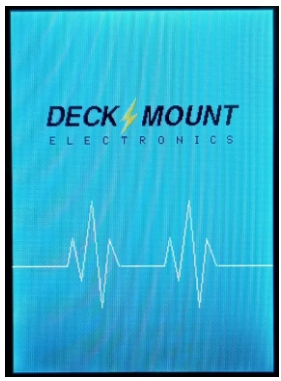
APAP	-	Automatic Positive Air Pressure
CPAP	-	Continuous Positive Air Pressure
S	-	Spontaneous Ventilation
T (VAPS)	-	Timed Ventilation
S/T (VAPS)	-	Spontaneous/Timed Ventilation
PC (VAPS)	-	Pressure Control
APCV	-	Assist Pressure Control Ventilation

Therapy Mode	Descriptions
APAP	Automatic Positive Air Pressure
CPAP	Continuous Positive Air Pressure
S	Spontaneous Pressure Support; A Bi-level therapy mode where breaths are patient-triggered and patient-cycled. The device triggers to IPAP (Inspiratory Positive Airway Pressure) in response to spontaneous inspiratory and cycles to EPAP (Expiratory Positive Airway Pressure) during exhalation. The device also cycles a patient-triggered breath if no patient exhalation effort detected for 3 seconds. The level of Pressure Support delivered is determined by the difference between IPAP and EPAP settings (PS = IPAP - EPAP)
T	Timed Pressure Support; A Bi-level therapy mode where breaths are machine-triggered and machine-cycled. T mode provides mandatory pressure assist with bi-level pressures. The patient's breathing rate has no effect the machine rate or pressure levels. The trigger to IPAP is determined by the breath rate setting, and the cycle time is determined by the inspiratory time setting.
S/T	Spontaneous/Timed Pressure Support; A Bi-level therapy mode where each breath is patient-triggered and patient-cycled or machine-triggered and machine-cycled. S/T mode is similar to S mode, except that the device also will enforce a set minimum breath rate by, if necessary, providing machine (time) triggered breaths. For these breaths, the inspiratory time is also a set value.
PC	Pressure Control
APCV	Assist Pressure Control Ventilation

4.2 STARTING / STOPPING THE THERAPY

Make sure your device is functioning properly each time before starting therapy.

1. Turn o ffthe device by pressing the power switch.
2. Inspect the device and all the provided accessories. If there are any visible defects, the system should not be used.
3. Check the integrity of the circuit configuration (device and provided accessories) according to the setup descriptions in this User Guide and that all connections are secure.
4. Press the power switch of the device once to turn on the device. The device is ready for use when the Treatment screen is displayed.

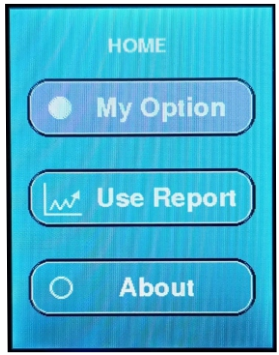


Therapy Mode
Press The Therapy button for Start, Press the Rotary button For Shift Page

4.3 WORKING WITH DEVICE MENU

1. The first screen, which appears after the successful boot is the “home screen".
2. The home page has three options , You can change the rotary upwards and downwards for select home screen options. You push the rotor then enter the selected options page.

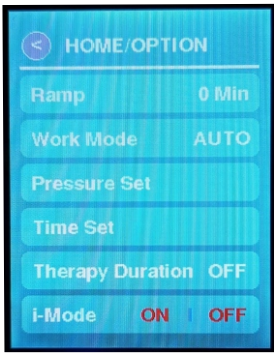
A. My Option
B. Use Report
C. About

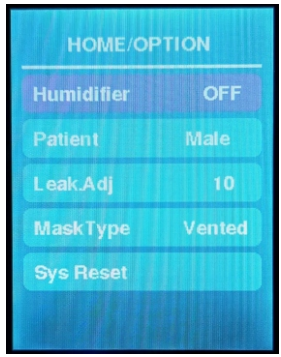


3. Home Screen >> My Option

4. This page have 12 options

A. **Home** - This is back to home screen
B. **Ramp**
C. **Work modes**
D. **Pressure set**
E. **Time set**
F. **Therapy duration**
G. **i-Mode**
H. **Humidifier**
I. **Patient gender**
J. **Leak adjust**
K. **Mask type**
L. **System reset**



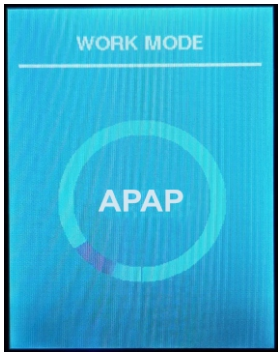


5. Home Screen >> My Option >> Ramp

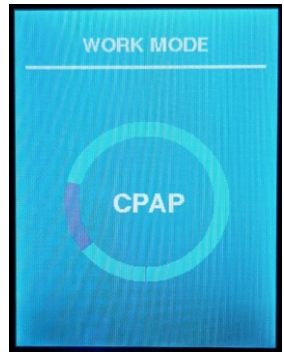
A. For Ramp Time

6. Home Screen >> My Option >> Work Mode

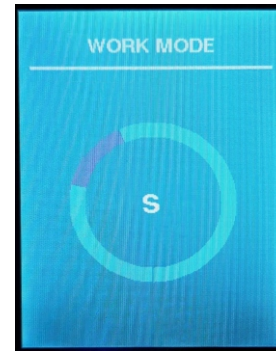
A. APAP Mode



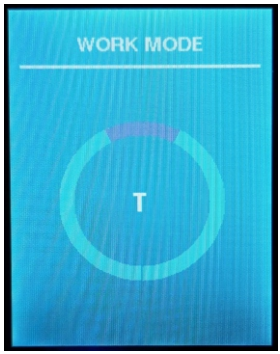
B. CPAP Mode



C. S Mode

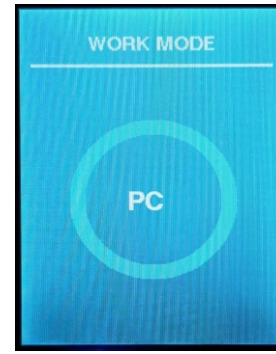


D. T Mode

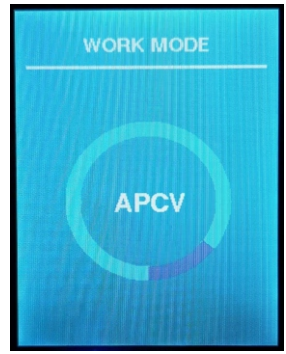


E. ST Mode

C. PC Mode



E. APCV Mode



4.4 PRESSURE SETTING OF WORKING MODES

Home Screen >> My Option >> Pressure setting

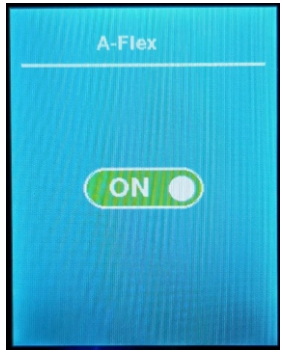
1.**Inspiratory Duration**- That is the timing of inhalation.
2.**Inspiratory Trigge**r- It is provide the pressure of inspiration in a set of time.
3.**Expiratory Trigger**- That is the expiration timing.
4.**Expiratory Relief**- Expiratory relief is provide timing tp exhalation air relief.
5. **Inspiratory Sense-** Sensation of inhalation.
6. **Expiratory Sense-** Sensation of exhalation.
7. **Max.P-** Maximum pressure of a therapy mode.
8. **Min.P-** Minimum pressure of a therapy mode.
9. **IPAP-** Inspiratory positive airway pressure.
10. **EPAP-** Expiratory positive airway pressure.
11. **TV-** Tidal volume.
12. **BPM-** Breath per minute.
13. **PEEP-** Positive end-expiratory pressure (PEEP) is the pressure in the alveoli above atmospheric pressure at the end of expiration.
14. **HEIGHT-** Height is set in CMs according to patient.

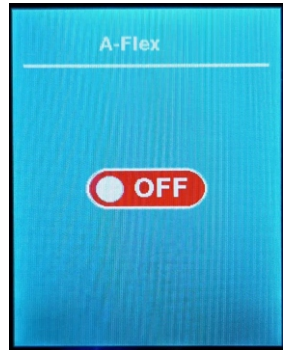
Home Screen >> My Option >> Pressure setting

For APAP Mode

Home Screen >> My Option >> Pressure setting >> A-flex

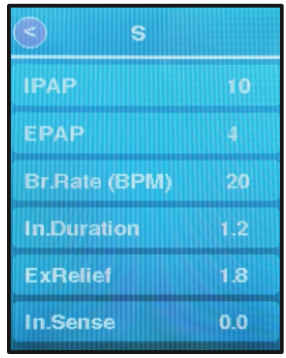
For APAP Mode with A-flex



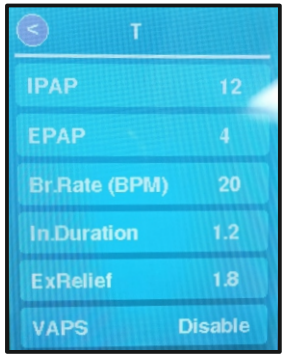


■ For CPAP Mode

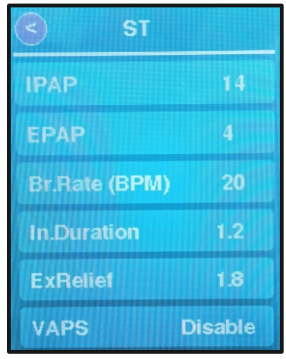
■ For S Mode



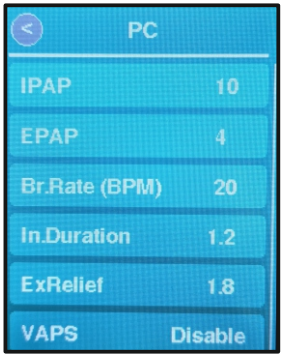
■ For T Mode



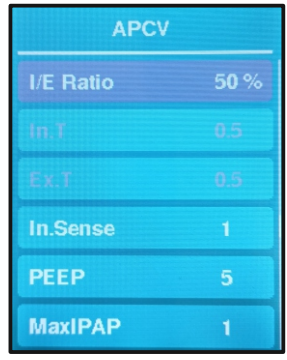
■ For ST Mode



■ For PC Mode

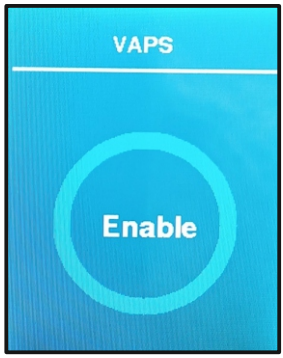


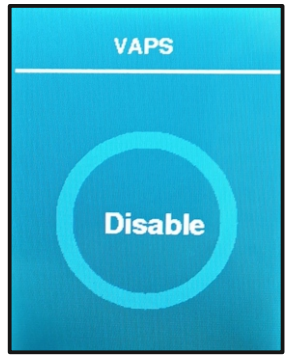
■ For APCV Mode



Home Screen >> My Option >> Pressure setting

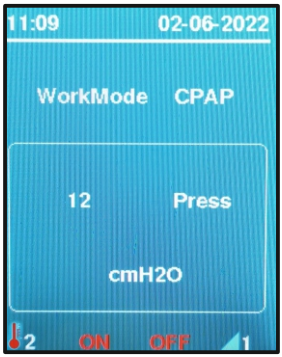
For T,ST,PC Mode with VAPS





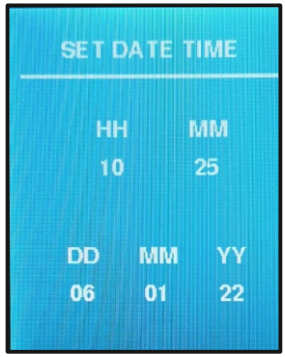
Display at running time

Press and hold the rotary one second for page shifting



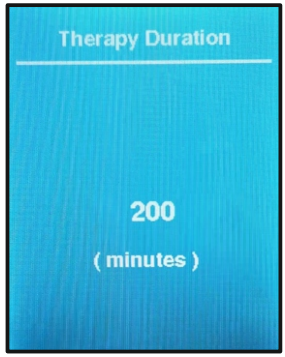
4.5 REAL TIME SETTING

Home Screen >> My Option >> Time set



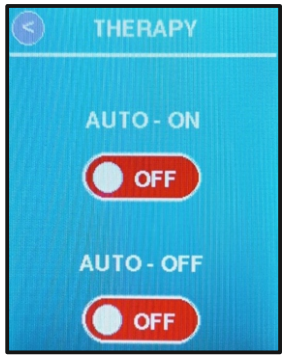
4.6 THERAPY DURATION- 10 to 600 minutes

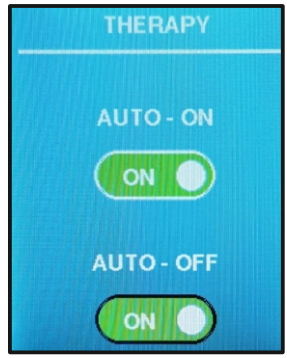
Home Screen >> My Option >> Therapy duration



4.7 i-mode On/Off

Home Screen >> My Option >> i-mode



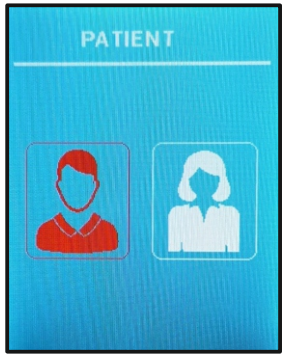


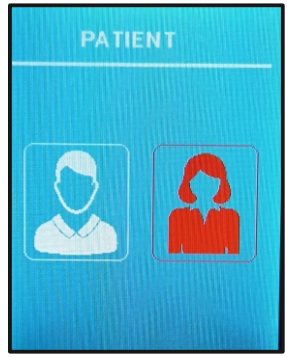
4.8 HUMIDIFIER - Level 0 to 5

Home Screen >> My Option >> Humidifier

4.9 PATIENT GENDER

Home Screen >> My Option >>Patient



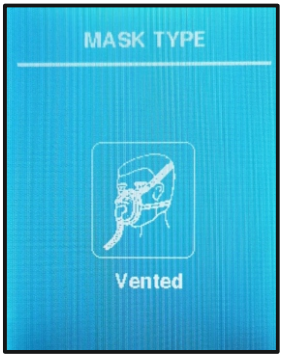


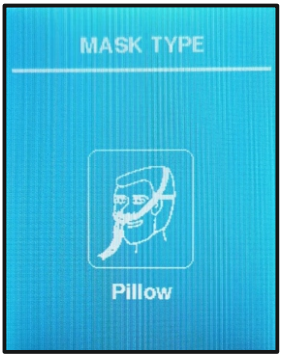
4.10 LEAK ADJUST - 0 to 10 ml

Home Screen >> My Option >> Leak adjust

4.11 MASK TYPE- VENTED/NASAL/PILLOW MASK

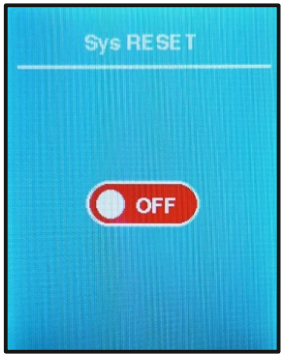
Home Screen >> My Option >> Mask type

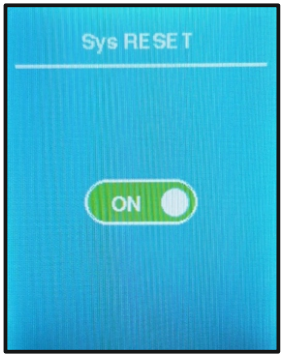


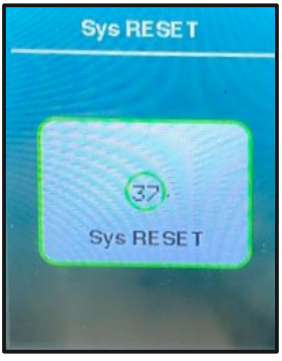


4.12 SYSTEM RESET - For Default

Home Screen >> My Option >>Sys reset

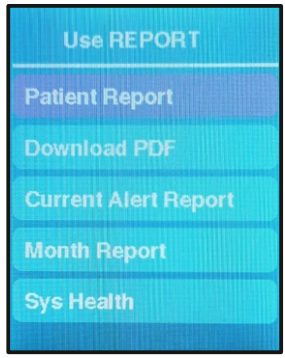






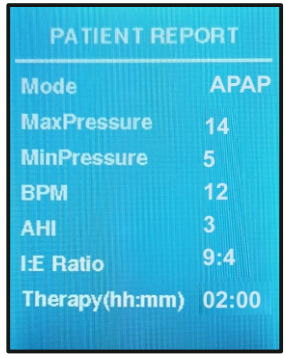
USE REPORT

Home Screen >> Use Report



4.13 PATIENT REPORT

Home Screen >> Use Report >> Patient Report

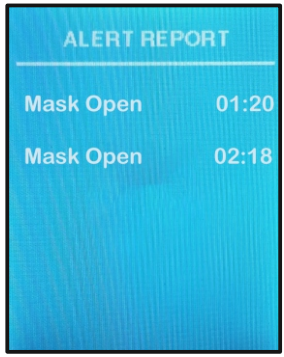


4.14 DOWNLOAD PDF

Home Screen >> Use Report >> Download pdf

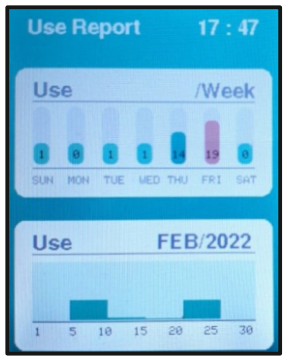
4.15 CURRENT ALERT REPORT

Home Screen >> Use Report >> Current Alert Report



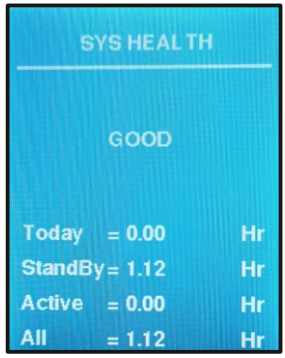
4.16 WEEK & MONTH REPORT

Home Screen >> Use Report >> Month report

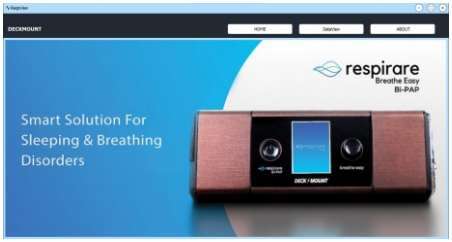


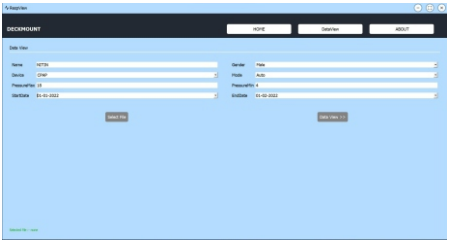
4.17 SYSTEM HEALTH

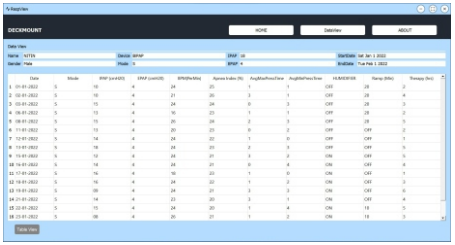
Home Screen >> Use Report >> Sys health

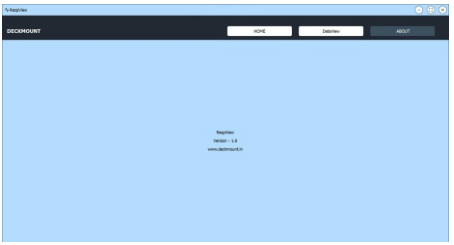


4.18 OFFLINE REPORT FORMAT









ABOUT

Home Screen >> About

Audible Alarm

When an alarm condition occurs, device will raise an audible alarm .

Alarm Condition:

Condition-1: This is not an alarm but an audible beep will occur confirming that device started and is ready for the therapy.

Condition-2: If therapy is on but mask is not fixed on the face of the patient, you will have 3 continuous buzzer beeps .

Condition-3: If therapy is running on ST Mode, and there is a shift from S Mode to T Mode, there will be 3 beeps in low volume.

4.19 TYPES OF ALERT

Alerts	Avialable	Error code
Mask Open	Yes	dm01
Auto On	Yes	dm02
Auto Off	Yes	dm03
Apnea	Obstructive Central Complex	dm04 dm05 dm06
Power	Yes	dm07

5 CLEANING, DISINFECTION & STERILIZATION

Face mask and tubing system are the only parts which require cleaning

STAGE - I Cleaning method

STEP-1: The cleaning of reusable parts usually begins soon after use. Soil is wiped from device surface with a moist sponge or towel. Masks and vented Tube, are usually placed in a basket or tray for transportation to the processing area.

STEP-2: Manual cleaning of the mask and components should be done under water in cool to lukewarm water (45 degree maximum) . Use a neutral pH (7) mild deter gent. Typical concentration of detergent is one ounce to 2 litre of water. Water Hardness, temperature and the type of the soil affect the effectiveness of the detergent. Use a small brush to clean the inner groove at the mask outlet and vented Tube. Additional cleaning supplies may be required to clean stubborn stains or hard to reach areas.

STEP-3: Mask and vented Tube, must be thoroughly rinsed with clean water to remove the detergent residuals and debris from the components.

STEP-4: Dry all components thoroughly using a clean cloth or disposable paper towels.

STAGE - II: Steam Sterilization (Silicon Rubber Face mask only)

Sterilization of the silicon rubber face mask can be achieved with steam sterilization. Type of Cycle — Gravity Displacement Temperature: 90 degree - 100 degree Type of Load — Wrapped Method Cycle Time: 7 — 10 minutes

STEP — 1: Face mask should be disassembled from vented Tube, Mask should be individually packaged in an acceptable packaging material and sterilized in a position that ensures adequate steam contact with all the surfaces.

STEP -2: Loading the sterilizer
Allow free circulation of steam around each mask. Position device in the sterilizer to allow adequate air elimination and drainage of condensate without wetting of other items in the load. While sterilizing, it is important that we follow the Manufacturer's instruction.

STEP-3: Unloading the sterilizer
All items removed from the sterilizer must remain in the sterilizer cart until adequately cooled. They shouldn't be touched during the cooling process.
Sterile items should be stored away from floors, ceiling or outside walls. They should be positioned so that the packaging is not crushed, bent or compressed.
Closed or covered cabinets are recommended for the storage of sterile packages.

6 WARNING AND CAUTIONS

Environment Temperature	Do not use this device if room temperature is more than 40°C because pressure unit of the device also generates heat. Do not use the device, if it is kept in direct sunlight .
Improperly Functioning device	If you notice any unexpected changes in the performance of the device, unusual sounds, if the device is dropped or water is spilled on the device - discontinue using the device and contact the supplier.
Cleaning	To avoid electrical shock, always unplug the power cord from the wall outlet before cleaning the device. Periodically inspect electrical cords and cables for damage or signs of wear. Discontinue use and replace if damaged. Never use water or heating element in cleaning the device. Do not use harsh detergents, abrasive cleaners, or brushes to clean the device
Electrostatic Discharge (ESD)	Do not use conductive tube/mask with the device
Extension Cords	Do not run the device on Extension Cord

The device may only be operated at temperatures between 5°C and 40°C (41°F and 104°F).

Periodically inspect the power cord for damage or signs of wear. Discontinue use and replace if damaged.

For optimum performance, have your machine serviced from the nearest authorized service centre every 6 months.

7 TECHNICAL SPECIFICATION

Modes	APAP, CPAP, S , T, ST, PC, APCV
Modes with VAPS	S,T,ST
Mode with Flex	APAP
Power Consumption	60 Watt
Breathe Rate	Upto 4-60 BPM (Titration Mode)
Pressure Range	4-30 cm H2O
Waveform	Flow/Pressure
Max leak flow compensation	25 L/min
Max Flow Rate	240 L/min
Weight	2 kg approx.
Maximum Input current	5.0 Amp
IPAP	upto 30 cm H2O
i-Mode / Auto On - Off	Yes
Patient Gender	Male / Female
Mask type	Vented / Nasal / Pillow
Humidifier	Level 1 - 5 / Automatic
System Reset	Yes
Set Therapy Hrs / Scheduling	10 - 600 min (10hrs)
Respiratory time	0.5 sec to 3.0 sec
Report	Patient report , Device report
Report details	*Online & Offline / QR Code
Alerts	Open Mask, Apnea, Hyponea (and more)
Apnea Detection	CSA & OSA
Auto Ramp	Yes

7.1 PRODUCT DATASHEET

Parameters	Values
Therapy Modes	APAP,CPAP,S,T,ST,PC,APCV
VAPS / Flex	S,T,ST/ APAP
Pressure Range	4 – 30 cm H_2O
Starting Ramp Pressure	Automatic adjustable
Display	2.8 inches **LCD**
Altitude compensation	Automatic
Data Storage capacity	8GB Micro SD card
Power Supply	12V/5A
Weight	2 kg approx.
Respiratory rate detection	4-60 BPM
Inspiration Time	0.5 sec – 3.0 sec
Notification type	Audio Alarms

8 WARRANTY STATEMENT

It is assured that product shall be free from defects in design material and workmanship affecting the normal operation of the product, for the specified warranty period. If we receive notice of such defects during the warranty period and the product is returned with freight prepaid, we will, at our sole option, repair or replace the defective product. Any such replacement may be new or equivalent in performance to new. Replacement parts will be warranted for only the unexpired portion of the original warranty. The warranty begins on the date of PURCHASE of the product (as shown on our packing note).

The warranty does not apply to defects in the product resulting from:

- Improper or inadequate maintenance
- Misuse i.e. not used in accordance with the instruction manual
- Unauthorized modification
- Repairs attempted by persons not authorized by manufacturer
- Abuse or accidental damage
- Any loss of parts
- Ingress of substances into the product
- Excessive wear and tear caused by careless or rough handling
- Damage caused when shipping a device using inadequate packing is the customer's responsibility
- Please use the original packing materials whenever possible

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ELECTRONICS

Warranty Card

Product Model Number / Name :.....

Date of Purchase :.....Seller Name.....

Customer Name.....

Address :.....

.....

E-mail :.....

My signature below acknowledges that I have read, fully understand and accept this limited warranty agreement.

Signature :.....

Date :..... Company Seal

Place :.....

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Corporate Office
Deck Mount Electronics Private Limited, 260, Udyog Vihar, Phase-4, Gurugram-122015, Haryana, India

Toll free : 1800-3092-499

Plant Address
KOC, AMTZ Campus Pragati Maidan, VM Steel Project S.O Visakhapatnam Pin-530031, Andhra Pradesh, India

Service care : wecare@deckmount.in