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 SOVEREIGN MEDICAL, INC
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nHale™

Bi-Level Positive Air Pressure Device Design Specification Sheet



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Bi-Level Positive Air Pressure Device Design Specification Sheet

nHale™ provides bi-level positive air pressure to support respiratory therapy for spontaneously breathing adults weighing over 30kg.

nHale™ is a cost-effective, single patient, reusable device that enables clinicians to follow medical protocol for non-invasive ventilation. The clear user interface facilitates respiratory therapy for patients suffering from COVID-19 disease in private homes, traditional healthcare facilities (e.g. hospitals, assisted living facilities, nursing homes), as well as spaces converted for the care of large numbers of COVID-19 patients (e.g. convention centers, university dormitories, etc.).

Features:

- Small footprint for maximum portability
- Adjustable inspiration pressure, expiration pressure, mandatory respiration rate, inspiration period, rise time, and pressure thresholds
- nHale™ Monitor software for optional computer-based set-up
- CSV data output

Benefits:

- Simple design, ease of use
- Compact for transport
- Authorized for at-home therapy
- Authorized for use with supplemental oxygen
- Affordable

Includes:

- nHale™ device
- Power transformer / adapter
- USB cable [2.0]
- Instructions for Use for Medical Professionals
- Instructions for Use for Patients
- nHale™ Monitor software
- Replacement filter

Third Party Accessories [not included]:

- FDA cleared CPAP / Bi-Level PAP mask
- FDA cleared 22mm respiratory tubing
- Fisher & Paykel Healthcare HC150 Respiratory Humidifier [510(K) number: K003973]

nHale™ has been authorized by FDA under an Emergency Use Authorization [EUA]; nHale™ is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the device; nHale™ has not been FDA cleared or approved.

SYSTEM

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Weight

1.65 lb / .75 kg

Dimensions (W x D x H)

5.0 in x 5.5 in x 5.8 in /
12.7 cm x 14.0 cm x 14.7 cm

Power Requirement

12VDC, 3A [transformer supplied]

Operating Range

4 to 20 cm H2O

Operating Temperature

10 to 35 degrees C

OPERATION

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Features –

- Spontaneous Respiration: Pressure changes triggered by patient's normal respiratory patterns
- Mandatory Respiration: Pressure changes occur at a set interval if not triggered by normal respiration

Pressures –

- 4 to 20 cm H2O
- Inspiration and expiration pressures adjustable in 1 cm H2O increments
- If inspiration pressure equals expiration pressure, nHale™ behaves as a CPAP machine
- Inspiration pressure must be greater than or equal to expiration pressure

BIOMETRICS

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- Respiration Rate (RR) cycles / minute
- IPAP, cm H2O: Actual patient pressure measured at the inspiratory plateau
- EPAP, cm H2O: Actual patient pressure measured at the expiratory plateau

ALARMS [Configurable on/off]

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Types –

- Failure to achieve therapy pressure
- Therapy pressure exceeded
- Failure to cycle (detects and alerts failure to change between inspiration and expiration pressures)
- General pressure failure (tube disconnect, mask off, blower failure)
- Maximum system pressure exceeded (alarm over 22 cm H2O)

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