







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

nHale $^{\mathbb{M}}$ has been authorized by FDA under an Emergency Use Authorization [EUA]; nHale $^{\mathbb{M}}$ is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the device; nHale $^{\mathbb{M}}$ 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 Range4 to 20 cm H2OOperating Temperature10 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)



