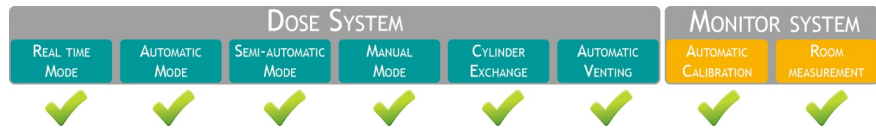


Automatic or Manual dosing Nitric Oxide Monitor



NOXtec 1000 is a medical device which both dosifies and monitors the supply of nitric oxide (NO).

NO is a gaseous vasodilator used to treat pulmonary arterial hypertension. It is supplied to the patients mixed with medical oxygen. NOXtec 1000 supplies a stable dosis throughout the therapy, even triggering an automatic exchange of the cylinders (it can harbour two cylinders) if needed.

NOXtec calculates automatically the necessary dosing flow, thanks to a disposable breathing flow sensor applied to the patient's circuit. Alternatively, the dosing flow can be set manually.

Thanks to the continuous sampling of the NO-O₂ mixture flow supplied, NOXtec is able to monitorize the NO concentration that the patient is receiving, and to check if this value is placed within predetermined thresholds.

NOXtec 1000 also monitors trace quantities of nitrous oxide (NO₂) in the mixture, a highly toxic gas which can compromise the patient's safety during the treatment. NOXtec 1000 triggers and alarm when this trace surpasses a threshold value.

MAIN FEATURES

- Dosing and monitoring modules and user interface independent from each other to guarantee the patient's safety.
- Automatic cylinder exchange to increase the treatment autonomy and optimize the gas consumption.
- Automatic venting procedure to minimize the NO₂ supplied to the patient at the beginning of the treatment and during the cylinder exchange, and also to depressurize the system when the device is not in use.
- Automatic calibration of the NO, NO₂ and O₂ sensors, available even when the device is dosing.
- Dosing mode options: Real time, Automatic, Semi-automatic or Manual.
- NOXtec includes an emergency manual dosing mode, which can be used even when the device is off.
- Negligible liberation of NO to the environment. The device includes a purge outlet to gather and canalize the residual gas.
- Measurement of the concentration of NO, NO₂ and O₂ in the room.
- Hot wire and differential pressure technologies for the external breathing flow sensors.
- Ethernet port for remote technical assistance.
- USB port to retrieve therapy data files.

NOXtec 1000: Basic Set

| REFERENCE | DESCRIPTION | QTY |
|-------------|--|-----|
| 01NXTC1000 | NOXtec 1000: Nitric Oxide Monitor with Automatic Deliver System. <i>Main Box with pneumatic, electronic and user interface.</i> | 1 |
| 01NTMNP0A | Manifold with calibration gas sensors: NO, NO ₂ y O ₂ , including PCB battery power. | 1 |
| 01NTDSEG1D | Flow sensor cable. | 1 |
| 01NTDSEGxx | Power cable "xx". | 1 |
| 10BiT3xxx0X | Stainless steel gas regulator for NO supply, with high pressure sensor incorporated. | 2 |

NOXtec 1000: Calibration Set

| REFERENCE | DESCRIPTION | QTY |
|--------------|--|-----|
| 10Bi02****0X | Stainless steel gas regulator for gas de calibration. | 1 |
| 01NTMNP019 | Gas calibration 5 L cylinder, 70 ppm of NO and 10 ppm of NO ₂ in N ₂ . | 1 |

NOXtec 1000: Optional Set

| REFERENCE | DESCRIPTION | QTY |
|------------|--|-----|
| 01NTCG0000 | Trolley for holding the device, space for 2 x 20 L cylinders, 1 x 5L calibration cylinder and 1x 5 L backup oxygen cylinder (<i>cylinders not included</i>). | 1 |



TECHNICAL SPECIFICATIONS

PHYSICAL SPECIFICATIONS

Dimensions and weight:

- Main unit: 205 x 300 x 345 mm; 9,2 kg.
- Cart: 1250 x 570 x 630 mm; 47,5 kg

Cart's capacity for cylinders: 2 cylinders of 20 L

Materials: AISI 304 and AISI 316L stainless steel, PTFE and ABS.

Screen: Touch colour 10,1" screen

DOSING MODULE

Dosing options:

- Real Time
- Automatic
- Semiautomatic
- Manual

Measuring range:

- Automatic: 0 - 4 L/min
- Manual: 0 - 0,02 - 0,03 - 0,05 - 0,07 - 0,1 - 0,15 - 0,2 - 0,25 - 0,3 - 0,45 - 0,6 L/min

NO dosing interval: 0-100 ppm (upgradeable upon request)

Dosing accuracy: $\pm 5\%$

Dosing resolution: 0,1 ppm

Ventilation range and accuracy:

| | | Adult | Paediatric and neonatal |
|-----------------------|----------|--|--|
| Differential pressure | Range | 2,0-120 L/min | 0,5-60 L/min |
| | Accuracy | $\pm 10\%$ or 0.5 L/min (whichever is higher) | $\pm 10\%$ or 0.2 L/min (whichever is higher) |
| Hot wire | Range | 0,5-100 l/min | 0,2-60 L/min (not available yet) |
| | Accuracy | $\pm 10\%$ or 0.1 L/min (whichever is higher) | (Not available yet) |

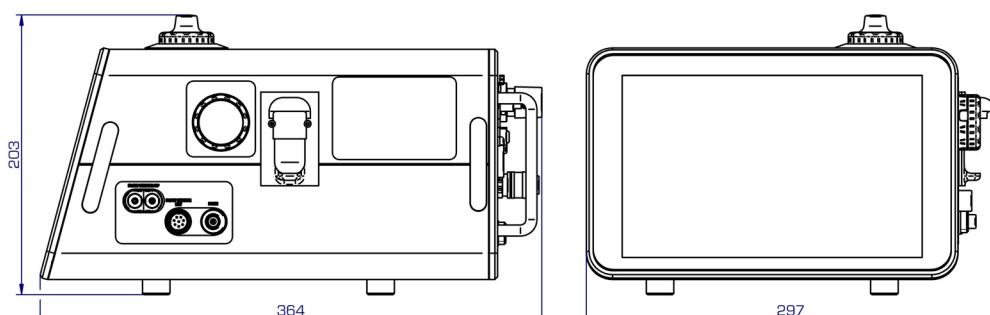
Set up time: < 2 min fs

MONITORIZATION MODULE

| | Gas sensor type | Measuring range | Measuring accuracy | Resolution | Response time |
|-----------------|----------------------|-----------------|---|------------|---------------|
| NO | Electrochemical cell | 0-160 ppm | $\pm 10\% + 0,5$ ppm | 0,1 ppm | <10s |
| NO ₂ | Electrochemical cell | 0-20 ppm | $\pm 10\% \dot{\pm} 0,2$ ppm (whichever is higher) | 0,1 ppm | <40s |
| O ₂ | Electrochemical cell | 0-100% | $\pm 3,5\%$ | 1% | <20s |

Sampling flow: 90 - 250 mL/min (configurable, 150 mL/min by default)

Operational life of the sensors: 12 months



OPERATING AND STORAGE CONDITIONS

Operating conditions: 10 - 40°C; 15 - 90% de humidity
Storage conditions: -10 - 60°C; 15 - 90% humidity

ELECTRICAL SPECIFICATIONS

Power: 100-240 VAC, 50-60 Hz

Battery:

- Duration: 4h
- Charging time: 2,5 h approx.

Classification: Clase I, type B

ELECTROMAGNETIC AND RF SPECIFICATIONS

Guidance and manufacturer's declaration - electromagnetic emissions

NOXtec is intended to be used in the electromagnetic environment specified below. The client or the user of NOXtec should ensure that it is utilized in such environment.

| Emission Test | Accordance | Electromagnetic environment - Guidance |
|---|------------|--|
| RF emissions CISPR 11 | Group 1 | NOXtec uses RF energy only for its internal function. Therefore, its RF emission are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR | Class B | NOXtec is suitable for use in all establishments, including domestic establishments and those directly connected to the low-voltage public network. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations / flicker emission IEC 61000-3-3 | Meets | |

IN COMPLIANCE

| | |
|------------------------------|---------------------------------------|
| CEN/TS 14507-1:2003 | UNE-EN 61000-4-2:2010 |
| CEN/TS 14507-2:2003 | UNE-EN 61000-4-3:2007/A1:2008/A2:2011 |
| UNE-EN 60601-1:2008/A12:2015 | UNE-EN 61000-4-4:2013 |
| IEC 60601-1-8:2006+A1:2012 | UNE-EN 61000-4-5:2015 |
| IEC 60601-1-6:2010/A1:2013 | UNE-EN 61000-4-6:2014 |
| IEC 62366-1:2015 | UNE-EN 61000-4-8:2011 |
| IEC 62304:2006/A1:2015 | UNE-EN 61000-4-11:2005 |
| UNE-EN 55011:2016/A1:2017 | UL requirements |
| UNE-EN 61000-3-3:2013 | RoHS Directive |