

Semiautomatic or manual dosing and Nitric Oxide Monitor

DOSE SYSTEM						MONITOR SYSTEM	
REAL TIME MODE	AUTOMATIC MODE	SEMI-AUTOMATIC MODE	MANUAL MODE	CYLINDER EXCHANGE	AUTOMATIC VENTING	AUTOMATIC CALIBRATION	ROOM MEASUREMENT
✗	✗	✓	✓	✗	✗	✓	✗



NOXtec 2000 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 2000 supplies a **stable dosis** throughout the therapy. The **dosing flow** is set on **semi-automatic** mode, once the user pre-set the respiratory flow and the dose in PPM on the screen of the device.

Thanks to the **continuous sampling of the NO-O₂ mixture flow** supplied, NOXtec 2000 is able to monitorize the NO concentration that the patient is receiving, and to check if this value is placed within predetermined thresholds.

NOXtec 2000 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 2000 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 calibration of the NO, NO₂ and O₂ sensors, available even when the device is dosing.
- Dosing mode options: Semi-automatic or Manual.
- 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.
- Ethernet port for remote technical assistance.
- USB port to retrieve therapy data files.

NOXtec 2000: Basic Set

REFERENCE	DESCRIPTION	QTY
01NXTC2000	NOXtec 2000: Nitric Oxide Monitor with Semiautomatic 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
01NTDSEGxx	Power cable "xx".	1
10BiT3xxxx0X	Stainless steel gas regulator for NO supply, with high pressure sensor incorporated.	2

NOXtec 2000: 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 2000: 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; 7,5 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:

- Semiautomatic
- Manual

Measuring range:

- Automatic: 0 - 1 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

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	$\pm 10\%$ ó $\pm 0,2$ 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

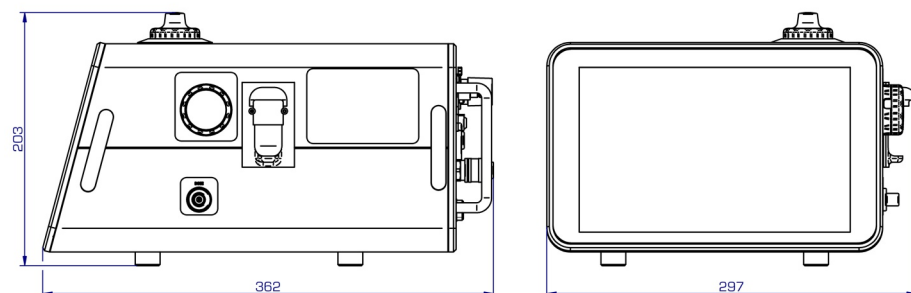
ELECTRICAL SPECIFICATIONS

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. NOXtec is suitable for use in all establishments, including domestic establishments and those directly connected to the low-voltage public network.
RF emissions CISPR	Class B	
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