NOXtec 2000

Semiautomatic or Manual dosing and Nitric Oxide Monitor

01NXTC2000

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 **manually**.

Thanks to the **continuous sampling of the NO-O_2 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 (NO_2)** 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, NO_2 and O_2 sensors.**
- NOXtec 2000 includes a **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**.

C/ Tungsteno 11-15.
Arganda del Rey, 28500, Madrid
Telf.: +34 91 871 99 50
www.itcsal.com itcsal@itcsal.com

CE 0051

ISO 13485 ISO 9001

01/2019-Rev.1

NOXtec 2000

Semiautomatic or Manual dosing and Nitric Oxide Monitor

01NXTC2000

NOXtec 2000: Basic set		
Reference	**Description**	**Qty**
01NXTC2000	NOXtec 2000: Nitric Oxide Monitor with Semiautomatic and Manual Deliver System ▪ Main box with pneumatic, electronic and user interface.	1
01NTMNPG0A	Manifold with calibration gas sensors: NO, NO_2 and O_2, including PCB battery power	1
01NTMGEGxx	Main cable "xx"	1
10BiT3xxxx0X	Stainless steel gas regulator for NO supply, with high pressure sensor incorporated.	1

NOXtec 2000: Calibration Set		
Reference	**Description**	**Qty**
10Bi02**0X**	Stainless steel gas regulator for NOXtec gas calibration.	1
01NTMNPG19	NOXtec gas calibration cylinder 5L cylinder. 70ppm of NO and 10ppm of NO_2 in N_2	1

NOXtec 2000: Optional Set		
Reference	**Description**	**Qty**
01NTCG0000	NOXtec Trolley for holding the device, space for 2x 20L cylinders, 1x 5L calibration cylinder and 1x5L backup oxygen cylinder (cylinders not included)	1

C/ Tungsteno 11-15.
Arganda del Rey, 28500, Madrid
Telf.: +34 91 871 99 50
www.itcsal.com itcsal@itcsal.com

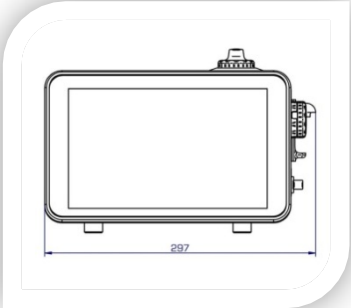
01/2019-Rev.1

NOXtec 2000

Semiautomatic or Manual dosing and Nitric Oxide Monitor

01NXTC2000

TECHNICAL SPECIFICATIONS



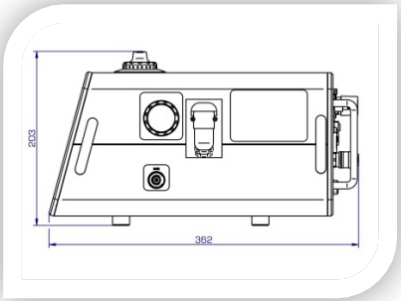
PHYSICAL SPECIFICATIONS

Dimensions and weight: **- Main unit:** 205 x 300 x 345 mm; 7.5 kg
- Cart: 1250 x 670x630 mm; 47.5 kg

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

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

Screen: Touch colour 10.1" LCD screen



DOSING MODULE

Dosing modes:

- Semiautomatic
- Manual

Flow positions:

- **NO flow semiautomatic mode:** 0-1 L/min
- **Flow positions manual mode:** 0 - 0.02 - 0.03 - 0.05 - 0.07 - 0.1 - 0.2 - 0.5 - 1 - 2 - 3 – 4 L/min

MONITORIZATION MODULE

	Gas sensor type	Measuringrange	Measuringaccuracy	Resolution	Response time
NO	Electrochemicalcell	0-160 ppm	±10% +5 ppm	0.1 ppm	<10s
NO_2	Electrochemicalcell	0-20 ppm	10% or ±0.2 ppm (whichever is higher)	0.1 ppm	<40s
O_2	Electrochemical cell	0-100%	±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% humidity
- Storage conditions: -10-60°C; 15-90% humidity

ELECTRICAL SPECIFICATIONS

Power: 100-240 VAC, 50-60 Hz

Battery:

- Duration: >4h
- Charging time:2.5h approx.

Normative:

- EN 60601-2:2007 + CORR: 2010 / IEC 60601-1-2: 2007
- EN 60601-1: 2006 + CORR:2010 + A11: 2011 + A1: 2013 + AC: 2014 + A12: 2014 / IEC 60601-1: 2005 + CORR: 2006 +CORR2: 2008 + A1:2012

Classification: Class I, Type B

C/ Tungsteno 11-15.
Arganda del Rey, 28500, Madrid
Telf.: +34 91 871 99 50
www.itcsal.com itcsal@itcsal.com

CE 0051

ISO 13485 ISO 9001

01/2019-Rev.1

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	Electromagneticenvironment - Guidance
RF emissionsCISPR 11	Group 1	NOXtec uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RFemission CISPR	Class B	NOXtec is suitable for use in all establishments, including domestic establishments and those directly connected to the low-voltage public network.
Harmonicemissions IEC 62000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Meets	

C/ Tungsteno 11-15.
Arganda del Rey, 28500, Madrid
Telf.: +34 91 871 99 50
www.itcsal.com itcsal@itcsal.com