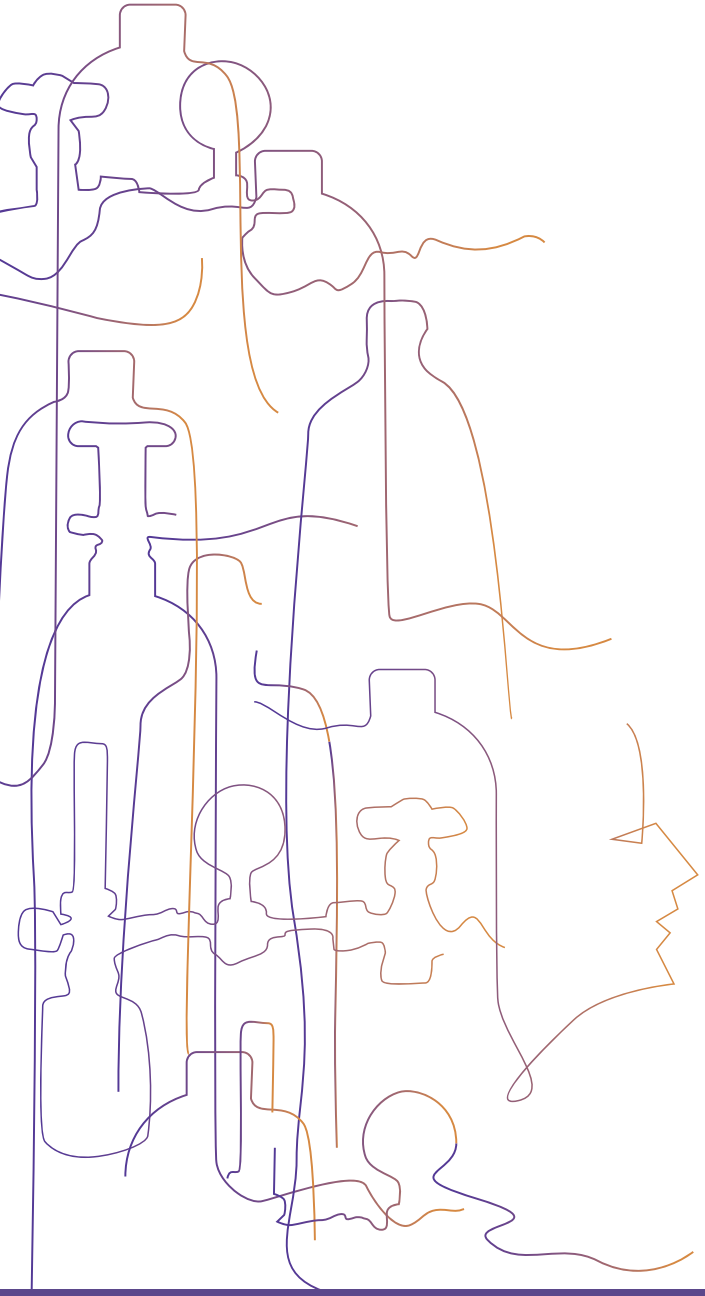
Novlead

INOwill N200

Nitric Oxide Generator and Delivery System



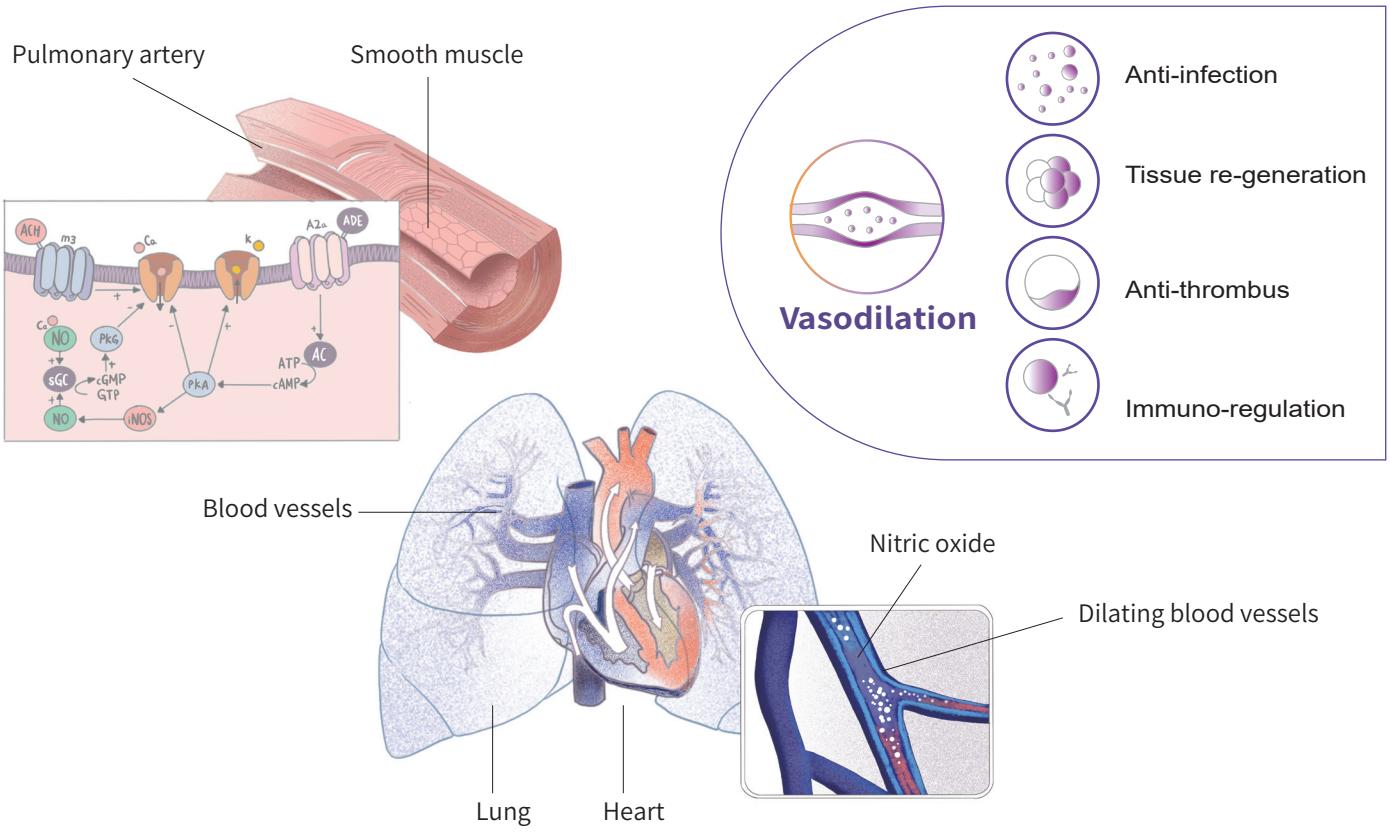
Say yes to **NO**

Novlead Biotech

Led by Science
Driven by Dedication

Nitric Oxide: the Miracle Molecule

As a "miracle molecule" recognized by the Nobel Prize in 1998, nitric oxide (NO) has been directly or indirectly used in medicine as a vasodilation drug for decades, and was later found to be an important endogenous gas molecule widely present in the human body that participates in various physiological processes. Its widely proven physiological mechanisms include vasodilation, anti-infection, stimulation of soft tissue regeneration, and immunoregulation.



Nitric Oxide for Pulmonary Hypertension Treatment

The effectiveness and safety of NO inhalation therapy in the treatment of acute and severe Pulmonary Hypertension (PH) and respiratory failure have been widely recognized by global clinical guidelines and practices. Following inhalation of nitric oxide, pulmonary vascular resistance decreases due to vasodilation, reducing right ventricular afterload while relieving pulmonary hypertension. The vasodilation increases blood flow in the pulmonary circulation and corrects the ventilation/blood flow (V/Q) ratio imbalance, subsequently improving oxygenation.

Clinical Classification of PH

Pulmonary Hypertension *

WHO group 1 Pulmonary arterial hypertension	WHO group 2 Pulmonary hypertension due to left-sided heart disease	WHO group 3 Pulmonary hypertension due to lung disease or hypoxia	WHO group 4 Chronic thromboembolic pulmonary hypertension and other pulmonary artery obstructions	WHO group 5 Pulmonary hypertension with multifactorial mechanisms
• Idiopathic • Heritable • Drug and toxin induced Associated with: • Connective tissue disease • HIV infection • Portal hypertension • Congenital heart disease • Schistosomiasis • WHO Group I'(pulmonary veno-occlusive disease and pulmonary capillary haemangiomatosis) • WHO Group I" (persistent pulmonary hypertension of the newborn)	• Left ventricular systolic dysfunction • Left ventricular diastolic dysfunction • Valvular heart disease • Specific congenital abnormalities	• Chronic obstructive pulmonary disease • Interstitial lung diseases • Other mixed restrictive orobstructive lung disease • Sleep-disordered breathing • Alveolar hypoventilation disorders • Chronic exposure to high altitude • Developmental lung diseases	• Chronic thromboembolic pulmonary hypertension • Other pulmonary artery obstructions (eg, angiosarcoma, other intravascular tumours, arteritis, congenital stenoses, and parasites)	• Haematological disorders (eg, sickle cell disease) • Systemic disorders (eg, sarcoidosis, Langerhans cell granulomatosis) • Metabolic disorders (eg, Gaucher's disease) • Others (eg, renal disease)

* Hoeper, M. et al. (2016). Classification of Pulmonary Hypertension. The Lancet Respiratory Medicine, 4 (4), P306-322

INOwill N-Series: the World's First Electrochemistry-Catalysis--Based Portable Nitric Oxide Inhalation Therapy Device

• On-Demand Generation: Tankless

With an electrochemical catalytic generation method, NO is supplied directly to the patient through an integrated gas delivery system without the need of storage cylinders.

• Smart Quantification: Intelligent

With a high-precision flow sensor that samples 250 times per second, inhaled nitric oxide (iNO) concentration concentration is instantly adjusted to flow changes. Precise control of the iNO concentration is guaranteed even under high frequency oscillatory ventilation. Intelligent algorithm is used to monitor and manifest the real-time remaining capacity (hours) of the NO generator cell.

• Real-Time Sensing: Precise

Patented phase-change stable sampling technology enables real-time monitoring of NO, nitrogen dioxide (NO_2) and oxygen (O_2) concentrations with high precision, to ensure safe and reliable clinical treatment.

• Reliable Safety: Safe

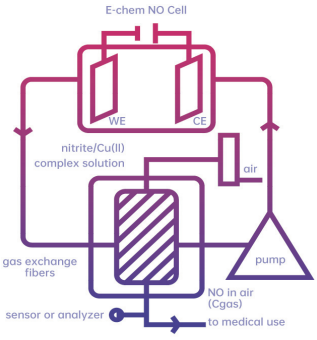
With significantly smaller size compared to a conventional high-pressure gas cylinder, one unit of INOwill generator cell can provide a steady supply of NO gas four times the capacity of the high-pressure gas cylinder, eliminating the safety risks and high costs associated with transporting and storing cylinders.

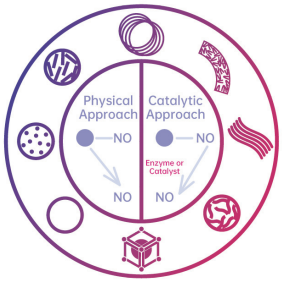
Core Technology

Integrating over 100 patents to establish a solid Nitric Oxide Generation Molecular Technology Platform (NOGMT)

NO On-Demand Generation

Electrochemical NO on-demand generation system featuring electrolyte solutions, catalysts and electrodes, integrated in a edge-cutting design.



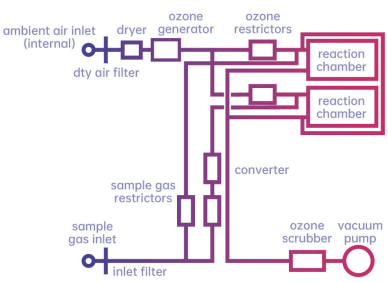


NO Controlled Release

Precise regulation of biochemical reactions, maintaining the balanced release and dynamic control of biomolecules within target concentration requirements, so that high-purity NO can be released spontaneously and stably.

Gas Molecule Sensing

Non-dispersive NO infrared sensor and electrochemical sensor are combined with an optimized gas sampling circuit structural module; special detection components are utilized for high-precision calibration.



Comparison of Different NO On-Demand Generation Technologies

Electrochemical Catalysis

The method utilizes an electric current to reduce nitrite ions to nitric oxide molecules in a solution containing sodium nitrite.

Metal ion complexes act as catalysts, enhancing the reaction efficiency.

The process only results in the production outcome of high-purity nitric oxide gas and water vapor.

$$X(|||)(L) + e^- \rightarrow X(|)(L)$$

$$X(|)(L) + NO_2^- + 2H^+ \rightarrow X(|||)(L) + NO + H_2O$$

Decomposition

The method involves the reversible decomposition of dinitrogen tetroxide (N_2O_4) intonitrogen dioxide(NO_2) under heating, followed by the reduction of nitrogen dioxide to NO_2 using vitamin Cas a reducing agent.

Both the ingredient (N_2O_4) and the intermediate product(NO_2) are toxic and volatile.

$$N_2O_4\,(g) \leftrightharpoons 2NO_2\,(g)$$

$$NO_2 + C_6H_8O_6 \rightarrow NO + H_2O + C_6H_8O_6$$

Plasma Discharge

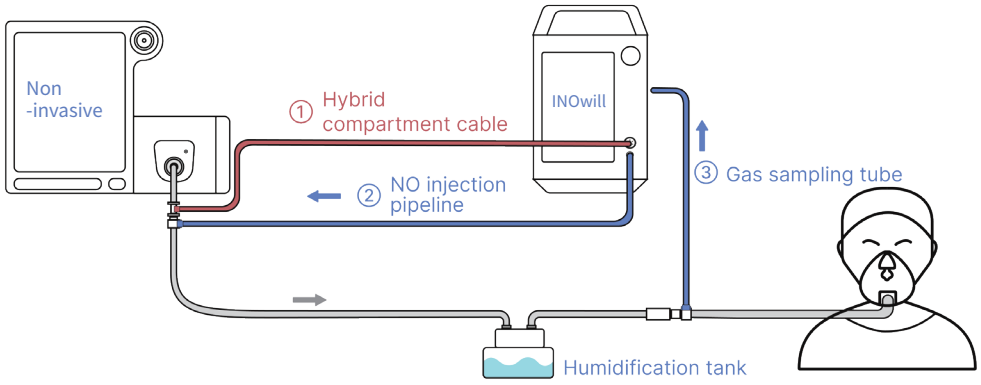
The method utilizes high-temperature plasma to dissociate N2and O_2 molecules into atomic free radicals, which then react to form NO via the Zeldovich Mechanism.

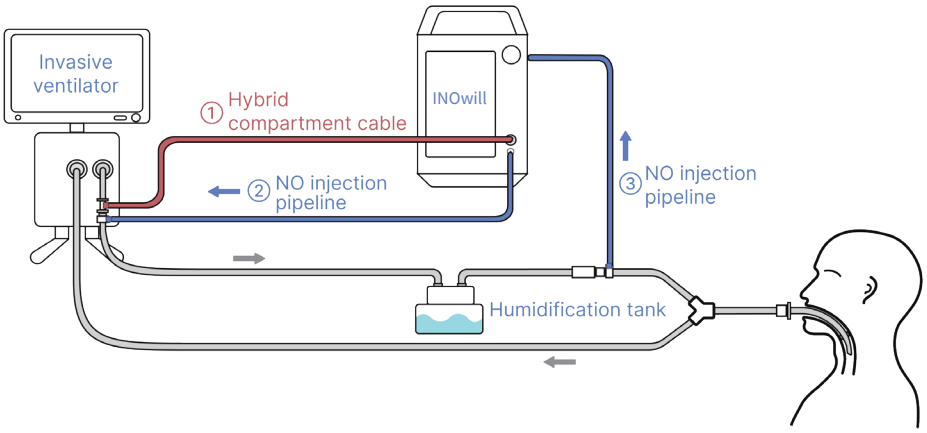
The resulting NO gas contains impurities and metal particles, requiring careful filtration before it can be used safely for medical purposes.

$$N_2 + O_2 \leftrightharpoons 2NO$$

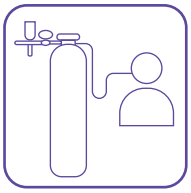
(also with NO_2, O_3, N_2O, etc.)

Concise Tube Connection for Multiple Scenarios





Technical Iteration of Nitric Oxide Inhalation Therapy



Cylinder Gas Era
(1999-2019)

- Inconvenient storage and transportation
- Space-consuming, with limited application scenarios
- High cost of comprehensive use

Portable On-Demand Generation Era
(2019-)

- Gas on-demand generation, with integrated delivery system
- Smart and portable, applicable to many scenarios
- Low costs of manufacture and transportation

Personalized Home Care Era
(2023-)

- Intelligent and well-integrated
- Compact and portable, suitable for both home and hospital use
- Revolutionary in terms of treatment applications and expense

INOwill N200 Nitric Oxide Generator and Delivery System

Patient Type	Neonate, child, adult
Intended Use	The INOwill Nitric Oxide Generator and Delivery System is intended to deliver nitric oxide, generated by the device, for inhalation therapy into the inspiratory limb of the patient breathing circuit in a way that provides a constant concentration of nitric oxide (NO), as set by the user, to the patient throughout the inspired breath.
NO Output Concentration	0-200ppm in steps of 1ppm
Monitoring Parameters	• NO concentration measurement range 0-200ppm, error not more than ±4% of reading or ±1ppm (whichever is greater) • NO_2 concentration measurement range 0-50ppm, error not more than ±4% of reading or ±1ppm (whichever is greater) • O_2 concentration measurement range 18%-100%, resolution 1%, error ⩽ ±(2.5%+2.5% of gas level)
Product Composition	Main Unit, Nitric Oxide Generator, Tube Accessories, Flow Sensor.
Dimensions	L x W x H: 41.2cm x 19.8cm x 38.5cm
Weight	15kg

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