

GLOSSARY OF TECHNICAL TERMS

This glossary of technical terms contains explanations of certain technical terms used in this document. As such, these terms and their meanings may not correspond to standard industry meanings or usage of these terms.

“AE”	adverse event, any untoward medical occurrence in a patient or clinical investigation subject, which does not necessarily have a causal relationship with the treatment
“ARDS”	acute respiratory distress syndrome, a type of respiratory failure characterized by rapid onset of widespread inflammation in the lungs and severe hypoxemia
“BPD”	bronchopulmonary dysplasia, a form of chronic lung disease that commonly affects premature newborns who have required mechanical ventilation and oxygen therapy
“breath-synchronized delivery”	an intelligent dosing mode where the device triggers gas delivery precisely during the patient’s inspiratory phase to optimize efficacy and reduce gas waste
“by-product management”	the technical processes of monitoring and filtering out undesirable gases, such as nitrogen dioxide, produced during nitric oxide generation
“CAGR”	compound annual growth rate, a measure used to describe the mean annual growth rate of an investment or business metric over a specified period of time
“CAP”	community-acquired pneumonia, an infectious disease of the lungs that is acquired outside of a hospital or healthcare facility
“cardiopulmonary homeostasis”	the state of steady internal physical and chemical conditions maintained by the heart and lungs in response to changing external environments
“CER”	Clinical Evaluation Report, a technical document that assesses and analyzes clinical data to verify the clinical safety and performance of a medical device in accordance with regulatory requirements
“chemical cassette approach”	a method of generating nitric oxide through a controlled chemical reaction initiated within a pre-packaged disposable cartridge or cassette
“chemiluminescence”	a high-sensitivity gas detection technology that measures the light emitted during a chemical reaction to determine the concentration of nitric oxide

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“closed-loop control”	an automated control mechanism where the system adjusts its output based on real-time feedback from sensors to maintain a target therapeutic level
“COPD”	chronic obstructive pulmonary disease, a chronic inflammatory lung disease that causes obstructed airflow from the lungs
“CRF”	case report form, a printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor on each trial subject
“CTCAE”	common terminology criteria for adverse events, a standardized classification and grading system used for the reporting of adverse events in clinical trials
“CVP”	central venous pressure, the blood pressure in the central veins, close to the right atrium of the heart, reflecting the amount of blood returning to the heart
“ECG”	electrocardiogram, a record or display of a person’s heartbeat produced by electrocardiography used for hemodynamic monitoring
“ECMO”	extracorporeal membrane oxygenation, a life support machine that provides prolonged cardiac and respiratory support to patients with severe heart or lung failure
“electrical impedance tomography”	a non-invasive imaging technique that provides real-time images of regional lung ventilation and perfusion
“electrolytic cell”	an electrochemical device that uses electrical energy to drive a non-spontaneous chemical reaction for nitric oxide generation
“ESG”	environmental, social and governance, a set of standards for a company’s operations that socially conscious [REDACTED] use to evaluate corporate responsibility
“fail-safe mechanisms”	design features that automatically revert a system to a safe condition in the event of a failure or malfunction to ensure patient safety
“FDA”	Food and Drug Administration, the federal agency of the United States Department of Health and Human Services responsible for regulating medical devices
“FeNO”	fractional exhaled nitric oxide, a quantitative measure used to assess airway inflammation, typically in patients with respiratory conditions

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“FIM”	first-in-man, a type of clinical trial where a new medical device or drug is tested on human subjects for the first time
“fluidic engineering”	the engineering discipline focused on the design and control of complex gas and liquid flow paths within a medical device
“gas-path architecture”	the structural design and logical configuration of internal airways, filters, and sensors within a gas delivery or monitoring device
“GB 9706”	a series of Chinese national standards for the safety and essential performance of medical electrical equipment
“GCP”	good clinical practice, an international ethical and scientific quality standard for designing, conducting, and reporting clinical trials
“guanylate cyclase–cGMP pathway”	a biochemical signaling pathway through which nitric oxide induces smooth muscle relaxation and vasodilation by increasing cGMP levels
“IABP”	intra-aortic balloon pump, a mechanical circulatory support device used to help the heart pump blood and improve myocardial oxygen perfusion
“ICU”	intensive care unit, a special department of a hospital that provides intensive care medicine for patients with life-threatening illnesses or injuries
“indication expansion”	the process of seeking regulatory approval to use a previously approved medical device or drug for additional clinical conditions or populations
“iNO”	inhaled nitric oxide, a clinical therapy that involves the inhalation of nitric oxide gas to treat various cardiopulmonary disease
“ISO 13485”	an international standard that specifies requirements for a quality management system for the design and manufacture of medical devices
“KOL”	key opinion leader, an influential expert in a specific clinical or scientific field whose opinions are respected and followed by the medical community
“MDR”	Medical Device Regulation, specifically referring to Regulation (EU) 2017/745, the legal framework governing the safety, clinical evaluation, and market placement of medical devices within the European Union

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“mechanical ventilation”	a form of life support where a machine helps a patient breathe when they are unable to breathe enough on their own
“methemoglobin”	a form of hemoglobin that cannot bind oxygen; its concentration is a key safety indicator monitored during nitric oxide therapy
“N ₂ O ₄ decomposition system”	a system designed to generate nitric oxide gas through the controlled thermal or chemical decomposition of nitrogen tetroxide
“NICU”	neonatal intensive care unit, an intensive care unit specializing in the care of ill or premature newborn infants
“NO ₂ adsorption media”	substances used in a gas-path architecture to selectively remove nitrogen dioxide from the therapeutic gas stream
“NT-proBNP”	N-terminal pro-B-type natriuretic peptide, a laboratory test used as a biomarker for the diagnosis and assessment of heart failure severity
“PCI”	percutaneous coronary intervention, a non-surgical procedure used to treat narrowing of the coronary arteries of the heart
“PH”	pulmonary hypertension, a type of high blood pressure that affects the arteries in the lungs and the right side of the heart
“plasma discharge”	an electrical discharge that ionizes gas, often air, into plasma and can occur in thermal high-temperature or non-thermal forms
“PMCF”	post-market clinical follow-up, a continuous process to update the clinical evaluation of a medical device after it has been placed on the market
“point-of-care production”	the capability to generate medical-grade gases directly at the site of patient care, eliminating the need for high-pressure gas cylinders
“ppb”	parts per billion, a unit of concentration used for the high-precision monitoring of trace gases in medical applications
“PPHN”	persistent pulmonary hypertension of the newborn, a serious condition where a newborn’s circulatory system fails to transition properly after birth
“ppm”	parts per million, a unit of concentration commonly used to define the therapeutic dosage of inhaled nitric oxide

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“precursors”	raw chemical substances or materials used as starting materials to generate therapeutic or diagnostic gases
“SAE”	serious adverse event, any adverse event that results in death, life-threatening experience, hospitalization, or significant disability
“SCI”	Science Citation Index, a citation index that covers thousands of the world’s most significant scientific and technical journals
“selective pulmonary vasodilation”	a physiological effect where inhaled nitric oxide relaxes pulmonary blood vessels without affecting systemic blood pressure
“SOP”	standard operating procedure, a set of detailed, written instructions to achieve uniformity in the performance of a specific function
“TEAE”	treatment-emergent adverse event, an adverse event that occurs or worsens after the administration of a treatment or device
“TFDA”	Taiwan Food and Drug Administration, the competent authority responsible for the management, safety, and quality of food, drugs, and medical devices in Taiwan China
“the Two Invoice System”	a regulatory policy in the PRC which requires a maximum of two invoices to be issued in the medical consumables distribution chain, with one invoice issued by the manufacturer to the distributor and the second invoice issued by the distributor to the medical institution
“tidal breath”	the normal volume of air displaced between normal inhalation and exhalation when extra effort is not applied
“titratable dosing”	the capability of a device to adjust the dosage of a therapy in precise, small increments to meet individual patient needs
“UDEM”	an EU designated Notified Body responsible for assessing the conformity of medical devices under the MDR framework to ensure they meet essential safety and performance requirements. For EEA regulations of Medical Devices, see “Regulatory Overview — Overview of Laws and Regulations in European Union — EEA Regulations of Medical Devices”