

## INDUSTRY OVERVIEW

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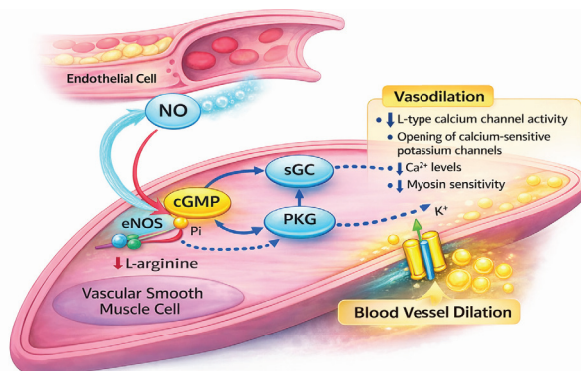
### GAS-BASED CARDIOPULMONARY THERAPEUTIC AND DIAGNOSTIC DEVICE MARKET OVERVIEW

Gas-based cardiopulmonary therapeutic and diagnostic devices form a subset of the broader cardiopulmonary device market, which covers tools used to diagnose, treat and support cardiovascular and respiratory diseases across the full continuum of care, from ICU to inpatient to outpatient and home settings. These devices use medical gases as a primary medium for clinical measurement, therapy delivery or mechanical actuation, and include systems for oxygen, inhaled nitric oxide (iNO) and aerosol therapies, analyzers that measure gas-related physiology or biomarkers such as exhaled nitric oxide (FeNO), CO and CO<sub>2</sub>, and gas-driven support platforms such as intra-aortic balloon pump (IABP).

#### GLOBAL iNO THERAPY MARKET

##### Overview of iNO Therapy

iNO is a selective pulmonary vasodilator delivered at titratable concentrations, typically 5 to 80 ppm in clinical use, into the inspiratory limb of a ventilator or breathing circuit through a dedicated delivery and monitoring system. By dilating pulmonary vessels in ventilated lung regions, iNO improves ventilation–perfusion matching, increases pulmonary blood flow to ventilated alveoli, lowers pulmonary arterial pressure and enhances arterial oxygenation while minimizing systemic hypotension.



Source: Literature Review, Frost & Sullivan Analysis

Over time, the industry has moved through several technology generations: (i) **Generation 1: Cylinder-based Systems:** Premixed high-pressure NO gas supplied as a drug product and delivered through dedicated monitoring systems; (ii) **Generations 2 and 3: Early Instant Generation:** Plasma discharge or N<sub>2</sub>O<sub>4</sub> decomposition systems that generate NO from room air or chemical cartridges, reducing dependence on industrial gas logistics; and (iii) **Generation 4: Advanced Instant Generation:** Electrochemical catalytic reduction systems that generate NO on demand.

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### Application Scenarios and Clinical Positioning of iNO Therapy

iNO therapy is used as a lung-selective pulmonary vasodilator across a range of acute cardiopulmonary settings, including: (i) NICUs for hypoxemic respiratory failure associated with PPHN; (ii) adult and pediatric cardiac surgery and congenital heart disease, including cardiopulmonary bypass procedures and heart/lung transplantation; (iii) adult and pediatric ICUs as supportive rescue therapy for severe hypoxemia or acute pulmonary hypertension with right-ventricular dysfunction; (iv) during cardiopulmonary bypass, where it is used to mitigate ischemia-reperfusion injury in organs and improve oxygenation; (v) high-altitude and community settings as an adjunct pulmonary vasodilator in conditions such as high-altitude pulmonary edema and other severe hypoxemic states; and (vi) investigational anti-infective regimens for viral community-acquired pneumonia and multidrug-resistant bacterial or fungal pneumonias, which remain under clinical trial.

### Major Indications for iNO Therapy

#### *Pulmonary Hypertension*

Pulmonary hypertension (PH) is a progressive cardiopulmonary disorder characterized by elevated pulmonary arterial pressure, vascular remodeling and right-ventricular strain. Imbalance between vasoconstrictors and vasodilators, including reduced NO signaling, contributes to sustained pulmonary vasoconstriction and right-heart overload. **Prevalence.** The global prevalent PH cases increased from 76.8 million in 2020 to 84.0 million in 2025. The number is expected to reach 90.4 million in 2030 and 96.6 million in 2035. Within this, China accounts for roughly one-fifth of the global PH pool. Prevalent PH cases in China increased from 14.5 million in 2020 to 15.4 million in 2025. The number is projected to reach 16.2 million in 2030 and 16.8 million in 2035. **Treatment Paradigm.** PH is generally managed according to the underlying cause and risk profile. Long-term pharmacological therapies targeting the endothelin, NO–cGMP and prostacyclin pathways have established efficacy in chronic disease control, but may involve systemic adverse effects, long-term treatment burden and, for certain advanced therapies, complex administration. Selected patients may also undergo interventional or surgical procedures, which may provide substantial clinical benefit in appropriate etiologies but are invasive and subject to patient eligibility and procedural availability. In acute, neonatal or peri-operative settings where pulmonary pressures remain elevated despite conventional measures, iNO provides rapid, titratable and predominantly lung-selective pulmonary vasodilation with comparatively limited systemic hemodynamic effects. In neonates with hypoxic respiratory failure associated with PPHN, iNO has demonstrated improvement in oxygenation and reduction in the need for ECMO in appropriately selected patients. Its role is principally supportive in acute settings rather than long-term disease control, and its use requires dedicated delivery and monitoring, with appropriate dose titration and gradual withdrawal to manage treatment-related clinical risks.

#### *Community-Acquired Pneumonia*

Community-acquired pneumonia (CAP) is a common and serious acute infectious lung disease that can progress to sepsis, ARDS and multi-organ failure, with high short-term mortality and readmission risk. **Incidence.** Globally, new CAP cases increased from 57.9 million in 2020 to 66.6 million in 2025. The number is expected to grow to 77.6 million in 2030 and 90.1 million in 2035. In China, annual CAP cases rose from 15.0 million in 2020 to 15.5 million in 2025. The number is expected to increase to 17.9 million in 2030 and 20.3 million in 2035. **Treatment Paradigm.** CAP treatment primarily comprises timely antimicrobial therapy where indicated, together with respiratory and hemodynamic support according to disease severity. Antimicrobial therapy directly addresses the underlying infection and represents the principal disease-directed treatment, although treatment effectiveness may vary depending on the causative pathogen and antimicrobial susceptibility. Oxygen therapy, HFNC, non-invasive or invasive ventilation and intensive-care support can maintain oxygenation and respiratory function in severe patients, but increasing levels of respiratory support may involve greater treatment complexity and invasiveness. In severe cases with refractory hypoxemia or acute right-ventricular strain despite standard measures, short-course iNO may be used as an adjunctive hospital-based therapy in selected patients. Through selective pulmonary vasodilation, iNO may improve oxygenation and reduce right-heart loading, complementing antimicrobial therapy and conventional respiratory support. Its use requires dedicated delivery and monitoring, with appropriate dose titration and gradual withdrawal to manage treatment-related clinical risks. High-concentration NO regimens for potential antimicrobial effects remain investigational.

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### *Acute Respiratory Distress Syndrome*

Acute respiratory distress syndrome (ARDS) is a severe form of acute respiratory failure that accounts for a significant proportion of ICU admissions and is associated with high mortality. It often develops as a complication of critical illnesses such as severe pneumonia and sepsis. **Incidence.** Global new cases of ARDS increased from 3.76 million in 2020 to 4.22 million in 2025. The number is projected to reach 4.61 million in 2030 and 4.99 million in 2035. In China, new ARDS cases increased from 0.65 million in 2020 to 0.79 million in 2025, reflecting post-pandemic recovery after temporary containment measures during COVID-19. The number is expected to steadily increase to 0.83 million in 2030 and 0.88 million in 2035. **Treatment Paradigm.** ARDS is primarily managed through treatment of the underlying cause and supportive critical care, including lung-protective ventilation, appropriate PEEP, prone positioning and, for selected refractory patients, ECMO. These measures are well-established, although more advanced supportive therapies may require substantial specialized resources and carry greater procedural complexity. In selected patients with persistent severe hypoxemia or right-ventricular strain despite conventional measures, iNO may rapidly improve oxygenation and reduce pulmonary vascular load, supporting its use as a short-term rescue or bridging therapy. The improvement in oxygenation may be transient, and a consistent mortality benefit has not been established in unselected ARDS patients. Its use requires appropriate delivery, monitoring and dose management.

### *Chronic Obstructive Pulmonary Disease*

Chronic obstructive pulmonary disease (COPD) is a common chronic respiratory disorder that imposes a substantial global healthcare burden. It is characterized by persistent respiratory symptoms and airflow limitation, driven by chronic inflammation that destroys alveolar walls, narrows and mucus-plugs airways, traps stale air and impairs gas exchange. In many healthcare systems, COPD continues to be associated with under-diagnosis, suboptimal long-term disease management and adherence, limited rescue options in severe exacerbations and inadequate control of severe hypoxaemia. **Prevalence.** Global prevalent cases of COPD grew from 222.3 million in 2020 to 262.2 million in 2025. Prevalent COPD is projected to increase to 302.7 million in 2030 and 347.1 million in 2035. Prevalent COPD in China increased from 105.3 million in 2020 to about 108.4 million in 2025. The number is expected to rise to 111.4 million in 2030 and 113.9 million in 2035. **Treatment Paradigm.** COPD is managed through a stepwise, guideline-directed approach focused on symptom control and prevention of exacerbations. Long-term management includes smoking cessation, inhaled bronchodilators, inhaled corticosteroids in selected patients, vaccination, pulmonary rehabilitation and long-term oxygen therapy where indicated. Acute exacerbations may require short-acting bronchodilators, systemic corticosteroids, antibiotics where appropriate, controlled oxygen therapy and non-invasive or invasive ventilation according to severity. iNO is not a routine guideline-recommended COPD treatment. Its potential role is limited to selected severe exacerbations with marked hypoxemia, ventilation–perfusion mismatch and suspected pulmonary hypertension or right-ventricular strain, where short-course lung-selective pulmonary vasodilation iNO may supplement conventional respiratory support. Longer-term use remains investigational and would require further evidence of clinical benefit, safety and cost-effectiveness.

## Global and China iNO Therapy Market Size

### *Market Size by Region*

For iNO, the historical market size was estimated primarily based on sales generated by relevant market participants. The forecast market size is derived using an indication- and utilization-based framework, taking into account (i) the underlying disease population, (ii) the clinically relevant high-risk patient subset, (iii) regulatory and commercial availability for the relevant indication, (iv) treatment penetration and treated-patient volume, (v) treatment frequency, duration and relative treatment intensity, (vi) hospital and system availability and utilization, (vii) recurring product usage, (viii) treatment pricing, and (ix) the technology mix between cylinder-based and instant-generation systems. No revenue contribution is assumed for an expansion indication before its modeled market availability, and penetration after market availability is assumed to increase gradually from a low initial level. The resulting forecasts are cross-checked against historical participant sales, installed-system utilization and technology mix.

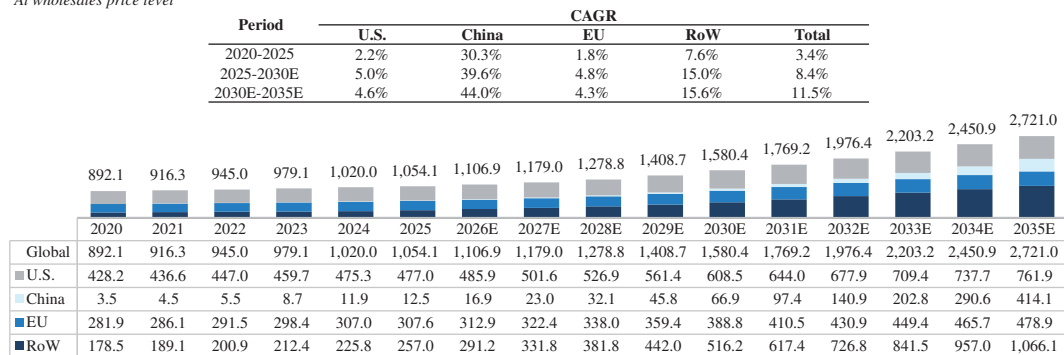
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The following chart depicts the historical and expected growth trajectories of global iNO therapy market by region from 2020 through 2035.

- The global iNO therapy market is estimated at approximately US\$1,054.1 million in 2025 and is projected to reach approximately US\$1,580.4 million in 2030E and US\$2,721.0 million in 2035E, representing CAGRs of approximately 8.4% and 11.5%, respectively.
- Growth differs materially by market maturity. The U.S. and EU are relatively established iNO markets with higher existing utilization and mature neonatal and critical-care workflows, and their growth is therefore expected to be supported mainly by recurring utilization, replacement and gradual adoption of newer delivery systems. China and RoW markets start from materially lower penetration and have greater scope for hospital adoption, increased treatment utilization and improved access. Longer-term growth additionally reflects potential expansion into new indications and care settings, subject to supporting clinical evidence and regulatory approvals.

### Global iNO Therapy Market Size and Forecast by Region, 2020-2035E

Unit: Million USD  
At wholesales price level



Note: The CAGR calculated here excludes the impact of exchange rate fluctuations.

Source: Frost & Sullivan Analysis

### Market Size by Technology

Instant generation technology is expected to gain share over traditional cylinder-based delivery, primarily due to its superior clinical continuity and safety profile, lower logistical burden and total cost of ownership, and a more compact footprint of approximately 1/5 that of traditional cylinders.

Globally, conversion from cylinder-based iNO to instant-generation products is expected to continue, although cylinder-based systems are unlikely to be fully displaced in the near term. The shift is supported by replacement cycles, physician and patient education, market development by industry participants, and evolving regulatory and quality requirements in certain markets. As hospitals typically consider upgrading or replacing the medical equipment and evaluating the contracts with suppliers in a five-year cycle, such replacement cycles give chances for instant generation providers to introduce their products. According to Frost & Sullivan, the projected transition toward instant-generation iNO technologies in established overseas markets is supported by continued clinical evidence generation, application expansion and market development. Industry participants sponsor clinical studies, collaborate with KOLs and present data at major professional meetings such as ATS, CHEST and ECCMID, helping build the evidence base for newer NO generation and delivery technologies. For example, Beyond Air has presented clinical data for its generator-based LungFit platform, while VERO Biotech has collaborated with clinicians from Northwestern/Lurie Children’s Hospital on the use of GENOSYL in neonatal inter-hospital transport. The industry is also expanding into broader indications and care settings. Beyond Air has investigated LungFit beyond PPHN, including viral pneumonia and NTM lung disease; Third Pole completed an FDA-IDE early feasibility study of portable eNOfit for ambulatory PH-ILD; and GENOSYL has expanded into settings including patient transport and MRI. Such developments broaden the potential clinical utility and application settings of cylinder-free systems. In parallel, hospital evaluations and demonstrations, clinical-user training, KOL/reference-hospital development, and local technical and after-sales support can reduce switching barriers from

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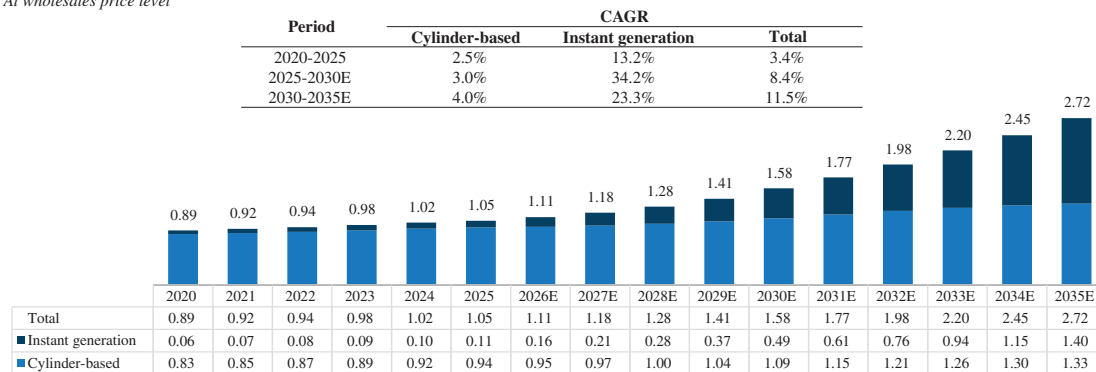
incumbent cylinder-based systems. Following FDA approval of LungFit PH, Beyond Air adopted a phased hospital introduction strategy involving evaluation, demonstrations and user training, with certain evaluated hospitals subsequently progressing to contracting. Together with periodic equipment replacement and procurement cycles, these activities provide hospitals with practical opportunities to reassess existing cylinder-based systems and support the gradual adoption of instant-generation technologies. Further growth is also supported by expansion beyond the existing cylinder-based market into additional indications and home-adjacent care settings.

The chart below depicts the historical and expected growth trajectories of global iNO therapy market by technology from 2020 through 2035.

- The global iNO therapy market is rebalancing its delivery mix from cylinder-based supply toward instant generation systems. From 2020 to 2025, cylinder-based segment increases from USD 0.83 billion to USD 0.94 billion, 2.5% CAGR, supported by U.S. and EU workflow inertia and low-cost industrial cylinders, while drug-grade cylinders are more clinically favored for quality assurance and, in practice, are supplied by only a limited number of pharmaceutical-gas players. Over the same period, instant generation grows from USD 0.06 billion to USD 0.11 billion, 13.2% CAGR. From 2025 to 2030E, instant generation reaches USD 0.49 billion, 34.2% CAGR, as portability and simplified logistics enable expansion beyond neonatal use into adult and non-traditional departments, and begin to open selected step-down and home-adjacent use cases in chronic respiratory disease management such as chronic obstructive pulmonary disease, enlarging the treated pool. By 2035E, instant generation rises to USD 1.40 billion, 23.3% CAGR, narrowing the gap and substituting parts of cylinder workflows.

### Global iNO Therapy Market Size and Forecast by Tech, 2020-2035E

Unit: Billion USD  
At wholesales price level



Source: Frost & Sullivan Analysis

In China, this shift is even more pronounced. The delivery mix shifted quickly, as conventional cylinder-based iNO therapy had not achieved broad adoption given the high cost of imported cylinders, and domestic instant-generation devices established the mainstream delivery model shortly after market entry, supported by guideline endorsement and market education.

The China iNO therapy market is estimated at approximately RMB90.1 million in 2025 and is projected to reach approximately RMB478.4 million in 2030E and RMB2,959.4 million in 2035E, representing CAGRs of approximately 39.6% and 44.0%, respectively. The projected growth principally reflects increasing treatment penetration from a low base, broader hospital and system adoption, increasing utilization of instant-generation systems and, over time, expansion into additional indications, rather than growth in the underlying disease populations alone.

The underlying disease populations provide a recurring clinical demand base but grow materially more slowly than the iNO market. Current treatment penetration remains low relative to the clinically relevant population. Within the PH-related clinically relevant population, implied treatment penetration is approximately 0.64% in 2025 and is projected to increase to approximately 2.50% in 2030E and 5.91% in 2035E. Increasing availability across NICU, ICU, cardiac-surgery and other critical-care settings, broader clinician familiarity and more standardized use are expected to expand the treated population and treatment utilization.

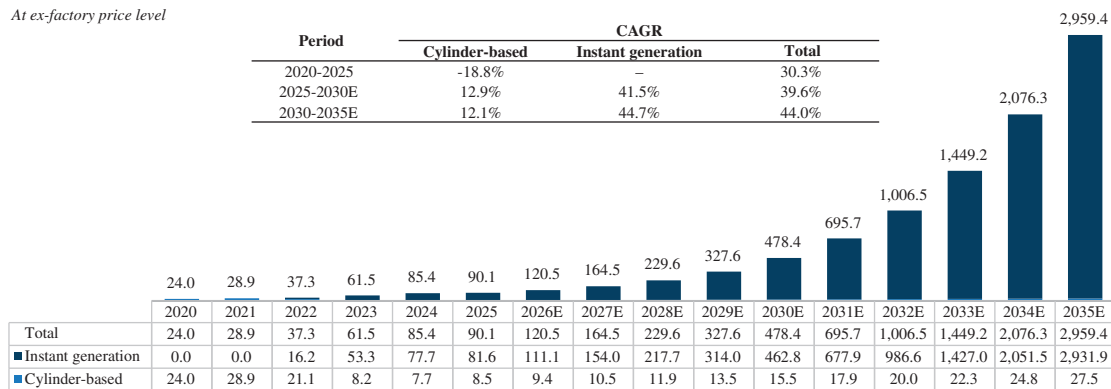
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Instant-generation systems provide a separate source of growth. The instant-generation segment is projected to increase from approximately RMB81.6 million in 2025 to RMB462.8 million in 2030E and RMB2,931.9 million in 2035E, while the cylinder-based segment is projected to increase from approximately RMB8.5 million to RMB15.5 million and RMB27.5 million, respectively. The forecast therefore reflects increasing system adoption and utilization rather than a material assumed increase in treatment pricing.

Additional indications contribute only after modeled market availability. ARDS and COPD are modeled to first contribute from 2029E and CAP from 2032E, with initial penetration of approximately 0.10% for ARDS and 0.05% each for COPD and CAP. Accordingly, growth from 2025 to 2030E is driven primarily by greater penetration of the existing PH-related market, hospital and system adoption and initial contributions from expansion indications, while growth from 2030E to 2035E increasingly reflects broader utilization and post-availability adoption of additional indications, subject to the relevant regulatory approvals.

### China iNO Therapy Market Size and Forecast by Tech, 2020-2035E

Unit: Million RMB  
At ex-factory price level



Source: Frost & Sullivan Analysis

On an indication-reconciliation basis, the global iNO therapy market in 2025 was approximately US\$1.054 billion and was attributable to PH-related indications, as the other modeled indications had not yet received the relevant regulatory approvals and therefore had no commercial market contribution. In 2030E, the PH, ARDS and COPD markets are projected to amount to approximately US\$1.516 billion, US\$54.6 million and US\$9.3 million, respectively, while CAP is assumed to have no commercial contribution, resulting in a total market of approximately US\$1.580 billion. In 2035E, the PH, ARDS, COPD and CAP markets are projected to amount to approximately US\$1.929 billion, US\$678.0 million, US\$105.4 million and US\$9.0 million, respectively, totaling approximately US\$2.721 billion.

On the same basis, China’s iNO therapy market in 2025 was approximately RMB90.1 million and was attributable to PH-related indications, as the other modeled indications had not yet received the relevant regulatory approvals and therefore had no commercial market contribution. In 2030E, the PH, ARDS and COPD markets are projected to amount to approximately RMB406.3 million, RMB46.9 million and RMB25.2 million, respectively, while CAP is assumed to have no commercial contribution, resulting in a total market of approximately RMB478.4 million. In 2035E, the PH, ARDS, COPD and CAP markets are projected to amount to approximately RMB1,102.0 million, RMB1,360.5 million, RMB474.3 million and RMB22.6 million, respectively, totaling approximately RMB2,959.4 million.

The projected contributions from ARDS, COPD and CAP are modeled only following assumed regulatory approval and commercial availability and remain subject to successful clinical development, regulatory approval and subsequent market adoption.

### Competitive Landscape

The global iNO therapy market is characterized by a limited number of specialized platforms approved in major markets. These products illustrate the coexistence of mature cylinder-based franchises with newer instant-generation solutions that differentiate through logistics, footprint, monitoring integration and potential extension into new indications and settings. The following chart sets forth the global competitive landscape of iNO therapy.

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| Company                  | Product                        | Mechanism                                             | Approved Indication                                                      | Latest Status                 |
|--------------------------|--------------------------------|-------------------------------------------------------|--------------------------------------------------------------------------|-------------------------------|
| <b>Novlead</b><br>(諾令生物) | INOWill® series                | Instant – electrochemical catalytic reduction         | Pulmonary hypertension in adults and pediatric patients                  | Approved (NMPA, CE)           |
| <b>BeyondAir</b>         | LungFit™ PH                    | Instant – plasma discharge                            | PPHN, peri- and post-operative pulmonary hypertension in cardiac surgery | Approved (CE, FDA)            |
| <b>Vero</b>              | GENOSYL® DS                    | Instant – N <sub>2</sub> O <sub>4</sub> decomposition | PPHN                                                                     | Approved (FDA)                |
| <b>Linde</b>             | Noxivent                       | Cylinder-based                                        | PPHN                                                                     | Approved (FDA, Health Canada) |
| <b>Air Liquide</b>       | KINOX™ + SoKINOX / NOXBOX-type | Cylinder-based                                        | PPHN, peri- and post-operative pulmonary hypertension in cardiac surgery | Approved (CE)                 |
| <b>Mallinckrodt</b>      | INOmax®                        | Cylinder-based                                        | PPHN, peri- and post-operative pulmonary hypertension in cardiac surgery | Approved (FDA, NMPA)          |

*Note: iNO therapy solution includes (i) premixed therapeutic NO supplied with, or for use with, a dedicated delivery and monitoring system and (ii) instant-generation platforms that generate NO at or near the point of care and integrate, or are supplied with, delivery and monitoring functions.*

*Source: FDA, NMPA, CE, Health Canada (as of LPD), Frost & Sullivan Analysis*

### Global Competitive Landscape for iNO Therapy by Revenue, 2025

| Rank | Company     | Market Share, % |
|------|-------------|-----------------|
| 1    | Company A   | 41.3%           |
| 2    | Company B   | 23.2%           |
| 3    | Company C   | 22.8%           |
| 4    | Company D   | 5.8%            |
| 5    | Company E   | 0.7%            |
| 6    | The company | 0.6%            |

*Notes:*

- Company A is a public company founded in 1879 and headquartered in Woking, the United Kingdom, listed on Nasdaq, focusing on industrial gases, medical gases, healthcare technologies and related services.
- Company B is a pharmaceutical company founded in 1867 and headquartered in Dublin, Ireland, focusing on specialty therapeutics, including inhaled nitric oxide therapy.
- Company C is a public company founded in 1902 and headquartered in Paris, listed on Euronext Paris, focusing on industrial and medical gases, healthcare technologies and related services.
- Company D is a private company founded in 2006 and headquartered in Atlanta, focusing on inhaled nitric oxide delivery systems for cardiopulmonary care.
- Company E is a public company founded in 2011 and headquartered in Garden City, New York, listed on Nasdaq, focusing on cylinder-free inhaled nitric oxide generation and delivery systems.
- The Company is a private company founded in 2018 and headquartered in Nanjing, focusing on the development and commercialization of gas-based cardiopulmonary therapeutic and diagnostic devices, including inhaled nitric oxide therapy.

*Source: Frost & Sullivan Analysis*

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The following chart sets forth the competitive landscape of iNO therapy in China.

### China Competitive Landscape for iNO Therapy

| Company                                                 | Product         | Mechanism                                     | Approved Indication                                                     | Latest Status       |
|---------------------------------------------------------|-----------------|-----------------------------------------------|-------------------------------------------------------------------------|---------------------|
| <b>Novlead</b><br>(諾令生物)                                | INOWill® series | Instant – electrochemical catalytic reduction | Pulmonary hypertension in adults and pediatric patients                 | Approved (NMPA, CE) |
| <b>Novlead</b><br>(諾令生物)                                | eNOaire® series | Instant – plasma discharge                    | Pulmonary hypertension                                                  | Approved (NMPA)     |
| <b>Respomed</b><br>(睿普)                                 | eNO series      | Instant – plasma discharge                    | Pulmonary hypertension                                                  | Approved (NMPA)     |
| <b>David</b><br>(戴維醫療)                                  | NOC series      | Cylinder-based                                | Pulmonary hypertension                                                  | Approved (NMPA)     |
| <b>Maian Pharma</b><br>(脈安醫藥)                           | AHMA-NO/O2-01   | Cylinder-based                                | Pulmonary hypertension                                                  | Approved (NMPA)     |
| <b>Mallinckrodt Lee’s Pharm</b><br>(李氏大藥廠) <sup>1</sup> | INOmax®         | Cylinder-based                                | Neonatal pulmonary hypertension                                         | Approved (NMPA)     |
| <b>ASCF</b><br>(航天長峰)                                   | ACM306          | Cylinder-based                                | Pulmonary hypertension, respiratory failure caused by acute lung injury | Approved (NMPA)     |

*Note:*

1. INOmax is commercialized in China by Lee’s Pharm under a license from Mallinckrodt.  
*Source: NMPA (as of LPD), Frost & Sullivan Analysis*

### China Competitive Landscape for iNO Therapy by Revenue, 2025

| Rank | Company     | Market Share, % |
|------|-------------|-----------------|
| 1    | The company | 42.7%           |
| 2    | Company F   | 26.6%           |
| 3    | Company G   | 22.0%           |
| 4    | Company H   | 1.7%            |

*Notes:*

1. Company F is a private company founded in 2019 and headquartered in Shenzhen, focusing on inhaled nitric oxide therapy devices based on instant nitric oxide generation technology.
2. Company G is a public company founded in 1994, with principal operations in China, listed on the Hong Kong Stock Exchange, focusing on the development, manufacturing and commercialization of pharmaceutical products.
3. Company H is a public company founded in 1985 and headquartered in Beijing, listed on the Shanghai Stock Exchange, engaging in medical devices, healthcare solutions and other high-technology businesses.

*Source: Frost & Sullivan Analysis*

### Drivers and Future Development Trends of iNO Therapy Market

Growth in the iNO therapy market is supported by (i) a large and recurring clinically relevant patient pool. In China, the estimated 2025 iNO-relevant pools include approximately 153.6 thousand PH-related patient-equivalents, 77.7 thousand severe or refractory CAP cases, 277.3 thousand severe or refractory ARDS cases and 542.2 thousand severe-exacerbation-equivalent COPD patients. PH remains the established core indication, while guideline dissemination and clinician education support appropriate patient identification and protocolized use; (ii) continued expansion of critical-care infrastructure, particularly in China, where as of 2020 ICU bed density remains approximately 3.6 beds per 100,000 people versus over 30 beds per 100,000 in the United States and Germany, according to Chen et al., 2024, implying that China remains a high-potential ICU market with rising demand for selective pulmonary vasodilators; The National Health Commission further set targets of 15 ICU beds and 10 convertible ICU beds per 100,000 population by the end of 2025, increasing to 18 and 12, respectively, by the end of 2027. Such capacity expansion supports hospital access to iNO but does not imply a one-for-one increase in iNO

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revenue; (iii) an evidence base in core indications, together with a technology shift from traditional cylinder-based delivery to instant-generation systems that reduce storage and logistics burdens and improve the economics and accessibility of NO supply; and (iv) in China, a more standardized coding and medical-service pricing framework. National medical-insurance information coding standards provide standardized classifications used in medical records, claims and DRG/DIP payment systems, but do not themselves establish a service price or reimbursement amount. Separately, the NHSA’s Respiratory System Medical Service Price Item Guideline (Trial), issued in March 2025, retained “nitric oxide inhalation therapy fee” as a separately identifiable medical-service price item, facilitating hospital charging and payment administration. This does not establish nationwide product reimbursement, uniform reimbursement ratios or a nationally fixed treatment price.

The iNO therapy market is expected to (i) shift from cylinder-based delivery to instant-generation, integrated NO platforms (including NO-enabled ventilators) to lower logistics burden and total cost of ownership, (ii) expand beyond acute rescue toward intermittent or longer-term use in selected PH and chronic lung disease patients, subject to supporting clinical and cost-effectiveness evidence, and (iii) increasingly favor systems with drug-grade assurance, reinforcing iNO as a standardized, regulated therapy and supporting a potential evolution toward drug-device combination positioning. In particular, for patients, instant-generation technology delivers high-purity iNO in real time, reducing reliance on cylinder storage, handling and replacement while enabling point-of-use generation and more continuous supply and treatment interruption caused by cylinder replacement. For hospitals, it removes the need for hazardous-material storage and complex cylinder logistics, lowers TCO through on-demand generation, and supports seamless intra-hospital transport with a highly portable device. Globally, the shift away from cylinder-based iNO has been gradual due to existing infrastructure and supply-chain inertia. In China, however, adoption has been faster and more transformative. Traditional cylinder-based iNO therapy was never widely adopted in the PRC, partly due to the treatment cost and operational requirements associated with cylinder procurement, storage and replacement. Regarding the cost of gas and consumables, based on an ex-factory price benchmark, cylinder-based iNO therapy costs approximately RMB218 per treatment hour, compared with approximately RMB10 per treatment hour for instant-generation iNO therapy in China, which may help reduce patients’ end-user treatment cost. Regarding the total cost of NO treatment, conventional cylinders typically cost \$57 per treatment hour, and iNO will therapy typically cost US\$7 per treatment hour. Instant-generation technology has therefore addressed a large unmet need and enabled the PRC market to effectively bypass the traditional cylinder-based model.

## GLOBAL IABP THERAPY MARKET

### Overview of IABP Therapy

IABP is the most widely used form of temporary mechanical circulatory support for patients with acute left-ventricular failure or cardiogenic shock and for selected high-risk cardiac procedures. A balloon-tipped catheter is positioned in the descending thoracic aorta and connected to an external console. The console inflates and deflates the balloon with helium in synchrony with the cardiac cycle, augmenting diastolic aortic pressure and coronary perfusion, modestly increasing cardiac output and reducing left-ventricular afterload and wall stress.

### Clinical Positioning and Application Scenarios

Consensus guidelines and expert statements position IABP as a targeted, short-term option within the broader temporary mechanical circulatory support (tMCS) ladder. Major cardiovascular societies and expert groups generally recommend selective use in acute myocardial infarction (AMI)-related cardiogenic shock. Within this framework, IABP is recognized for providing hemodynamic support through diastolic augmentation with relatively simple operation, a shorter learning curve and broad availability, and is typically used for as a bridge to recovery, definitive intervention or escalation—most commonly in acute heart failure and cardiogenic shock, perioperative support for high-risk PCI (especially within cardiology, with high-risk PCI accounting for around 30% of all PCI procedures), and support in cardiac surgery and in catheter laboratories and ICUs.

### Major Indications for IABP

#### *Cardiogenic Shock*

Cardiogenic shock is a severe form of acute circulatory failure caused by primary cardiac pump failure, leading to systemic hypo perfusion and a high risk of multi-organ dysfunction. Management is time-critical and focuses on optimizing myocardial metabolism and providing comprehensive supportive care. **Incidence.** Globally, new cardiogenic shock cases increased from 0.91 million in 2020 to 1.15 million in 2025. The number is projected to rise to 1.36 million in 2030

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and 1.52 million in 2035. In China, new cardiogenic shock cases increased from 0.24 million in 2020 to 0.31 million in 2025. The number is expected to grow to 0.39 million in 2030 and 0.48 million in 2035. This persistent growth is backed by accelerated population aging, which imposes a heavy disease burden that is only partially offset by long-term population decline. ***Treatment Paradigm.*** Cardiogenic shock is managed as a medical emergency in coronary care units, ICUs or catheterization laboratories, with initial treatment focused on rapid hemodynamic stabilization using oxygen or ventilatory support, optimization of intravascular volume and vasoactive drugs. For some patients who require additional support, temporary mechanical circulatory support devices, including IABP, are used in specialized centers to maintain systemic perfusion and support myocardial recovery or transition to longer-term therapies. Within this framework, IABP is positioned as a short-term, accessible form of mechanical circulatory support for selected cardiogenic shock patients; through synchronized balloon inflation and deflation in the descending aorta, it augments diastolic coronary perfusion, reduces left ventricular afterload and improves organ perfusion, and is typically used as a bridge to definitive revascularization, surgical intervention or transition to other forms of mechanical support. Compared with supportive care alone, IABP provides additional short-term mechanical circulatory support in selected patients, and compared with stronger temporary MCS devices, it generally offers greater simplicity, broader accessibility, lower cost and fewer bleeding and vascular complications.

### ***Acute Heart Failure***

Acute heart failure (AHF) refers to a rapid onset or worsening of heart failure symptoms over a short period of time, with abrupt worsening of dyspnea, congestion and/or hypoperfusion. It often presents as acute left or right heart failure or cardiogenic shock. AHF is a leading cause of hospitalization in patients aged over 65 years and is associated with high mortality and rehospitalization rates. ***Incidence.*** Globally, new AHF cases increased from 4.72 million in 2020 to 5.14 million in 2025. The number is projected to rise to 5.57 million in 2030 and 6.01 million in 2035. China’s growth is expected to accelerate. New incidences of AHF in China increased from 0.91 million in 2020 to 0.97 million in 2025. The number is projected to rise to 1.05 million in 2030 and 1.15 million in 2035. ***Treatment Paradigm.*** AHF is managed in emergency departments, coronary care units and ICUs, with early risk stratification based on congestion and peripheral perfusion. Initial management focuses on stabilizing airway, breathing and circulation to relieve congestion, careful fluid management, and close monitoring of renal function and electrolytes. Vasodilators may be used in patients with elevated blood pressure and adequate perfusion to reduce preload and afterload. For selected high-risk patients who remain unstable, temporary mechanical circulatory support including IABP provides short-term support by augmenting diastolic coronary perfusion, reducing left-ventricular afterload and improving cardiac output, and is generally used as a bridge to cardiac recovery, long-term device implantation or heart transplantation. Compared with vasoactive therapy and supportive care alone, IABP provides short-term hemodynamic support in selected unstable patients, and compared with stronger temporary MCS, it offers a more accessible and lower-cost bridging option.

IABP provides synchronized diastolic augmentation and reduction of left-ventricular afterload through a relatively familiar and widely available form of temporary mechanical circulatory support. Compared with vasoactive therapy and supportive care alone, it provides additional short-term hemodynamic support in appropriately selected unstable patients. Compared with more advanced temporary mechanical circulatory support such as microaxial pumps or VA-ECMO, IABP generally provides a lower level of circulatory support but is less complex to deploy and is more broadly available. Its limitations include vascular complications, bleeding and limb ischemia, and routine use in unselected acute myocardial infarction-related cardiogenic shock has not demonstrated a consistent mortality benefit. Clinical use is therefore patient- and scenario-specific. From a pricing and reimbursement perspective, IABP generally entails lower treatment-related costs than ECMO. Under Chongqing’s 2026 medical-service pricing framework for tertiary hospitals, IABP installation is priced at approximately RMB2,228 per procedure and ongoing monitoring at approximately RMB32 per hour, compared with approximately RMB2,000 and RMB134, respectively, for ECMO. IABP installation is classified as a Class B reimbursable item, under which patients are required to make a 20% upfront contribution before the remaining eligible amount is reimbursed at the applicable medical-insurance rate, while ECMO installation is classified as Class A and does not require such upfront patient contribution. Ongoing monitoring for both IABP and ECMO is classified as Class B. Accordingly, although their installation charges are broadly comparable, ECMO carries an ongoing monitoring charge of approximately four times that of IABP.

### **Synergy Between IABP and iNO Therapy**

In acute cardiopulmonary failure, management in ICUs often requires coordinated use of multiple devices to maintain circulation, ventilation and gas exchange, particularly in patients with cardiogenic shock, severe right ventricular failure with PH or escalating instability despite medication. In this setting, IABP and iNO provide complementary biventricular support — IABP supports systemic perfusion by improving coronary perfusion and reducing LV afterload, while iNO reduces PVR and RV afterload and improves oxygenation.

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### Global and China IABP Market Size

#### Global IABP Market Size

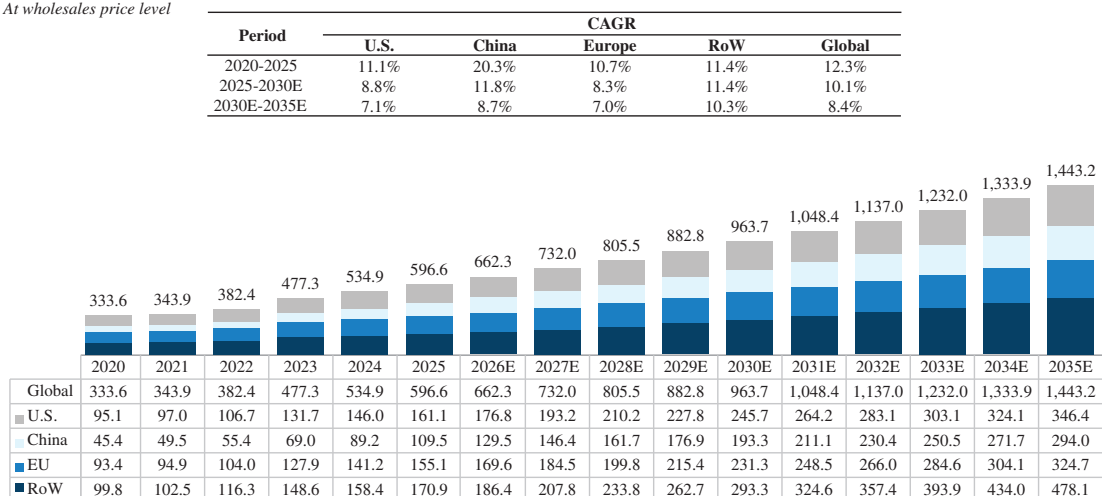
From 2020 to 2025, the global IABP market rose from USD 333.6 million to USD 596.6 million, CAGR 12.3%, supported by normalization of acute cardiac care and continued use in acute myocardial infarction with cardiogenic shock, acute decompensated heart failure, and high-risk percutaneous coronary intervention. The global IABP market is projected to expand from US\$596.6 million in 2025 to US\$1,443.2 million in 2035.

In 2025, the United States and Europe accounted for 27.0% and 26.0% of the global market, respectively, reflecting their sizable installed bases and established clinical adoption. By 2035, they are expected to remain substantial markets, accounting for 24.0% and 22.5%, respectively, supported by equipment replacement and recurring balloon-catheter utilization. In comparison, China accounted for only 18.4% of the global IABP market in 2025, indicating comparatively lower commercial penetration. China’s share is expected to increase to approximately 20.4% by 2035, narrowing the gap with the United States and Europe. Growth is expected to be supported by expansion from a lower installed base, broader cath-lab and critical-care capacity, penetration into lower-tier hospitals, and increasing domestic supply. Expansion of the installed console base will also generate recurring demand for single-use balloon catheters, supporting growth across both equipment and consumables.

Pneumatic helium systems represent a mainstream and mature IABP technology pathway. In 2025, pneumatic helium systems accounted for 37.3% of the global IABP market, equivalent to US\$222.6 million. Their market share is projected to increase steadily to 46.0% by 2035, potentially making pneumatic helium systems the leading technology pathway globally. The gradual share gain reflects the expected contribution of new Chinese pneumatic entrants, continued clinical familiarity with pneumatic helium systems and further development of intelligent pneumatic drive control, rather than rapid displacement of alternative designs. For a new pneumatic platform, alignment with an established technology pathway should facilitate clinical acceptance and reduce the market education required for an unfamiliar operating mechanism, although product-level adoption will continue to depend on performance, reliability, regulatory evidence, catheter compatibility and after-sales support.

#### Global IABP Market Size and Forecast, Breakdown by Region, 2020-2035E

Unit: Million USD  
At wholesales price level



Note: The CAGR calculated here excludes the impact of exchange rate fluctuations.

Source: Frost & Sullivan Analysis

#### China IABP Market Size

The following chart depicts the historical and expected growth trajectories of China IABP market size from 2020 through 2035.

For IABP, the historical market size was estimated principally based on sales revenue of relevant market participants. The forecast takes into account relevant acute cardiac-event and patient populations, hospital and cardiovascular-center adoption, cath-lab and critical-care capability, procedural utilization, domestic and imported product availability and pricing trends. Publicly available installed-base and procedure-volume data are used only as supplementary market context where comparable and are not applied as independent quantitative forecast inputs because their geographic scope, reporting periods and statistical definitions are not consistently comparable.

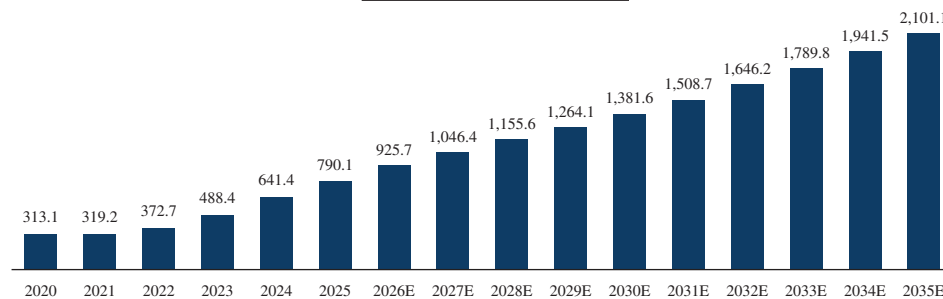
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The China IABP market is estimated at RMB790.1 million in 2025 and projected to reach RMB1,381.6 million in 2030E and RMB2,101.1 million in 2035E, representing CAGRs of approximately 11.8% and 8.7%, respectively. The underlying acute cardiac-event pool continues to expand, with annual cardiogenic shock cases increasing from approximately 0.31 million in 2025 to 0.39 million in 2030E and 0.48 million in 2035E, and AHF cases increasing from approximately 0.97 million to 1.05 million and 1.15 million, respectively. More importantly, the forecast reflects increasing penetration from a relatively low installed base, continued expansion of cath-lab and critical-care capacity, broader adoption in cardiovascular centers and tier-two hospitals, and increasing domestic supply, which may improve product availability, affordability and supply assurance. Expansion of the installed console base also supports recurring demand for single-use balloon catheters. Growth is expected to moderate over time as penetration increases and the market becomes more mature.

### China IABP Market Size and Forecast, 2020-2035E

Unit: Million RMB  
At ex-factory price level

| Period     | CAGR  |
|------------|-------|
| 2020-2025  | 20.3% |
| 2025-2030E | 11.8% |
| 2030-2035E | 8.7%  |



Source: Frost & Sullivan Analysis

### Competitive Landscape

Commercial supply of IABP consoles is highly concentrated globally. Teleflex and Maquet have U.S.-based manufacturing entities, while MERA/Senko is based in Japan, and the newly approved domestic manufacturers are based in China. Accordingly, commercial-scale manufacturing capability for IABP consoles is currently concentrated among a limited number of manufacturers across the United States, Japan and China.

IABP development requires integrated capabilities across drive control, ECG and arterial-pressure triggering, real-time synchronization, balloon-catheter compatibility, redundant power and alarm systems, and continuous-operation reliability, together with stringent regulatory and quality requirements. For example, FDA validation of Teleflex’s AC3 covered multiple balloon sizes and 216–218 hours of continuous operation, while the Cardiosave recall further highlights the critical reliability requirements for IABP consoles.

### Global Main Competitors for IABP

| Company         | Product                                    | Drive Type                        | System Design                                    |
|-----------------|--------------------------------------------|-----------------------------------|--------------------------------------------------|
| <b>MERA</b>     | Corart BP3                                 | • Electric-powered cylinder drive | • Integrated design<br>• No safety isolation box |
| <b>Teleflex</b> | AC3 Optimus™ IABP<br>AC3 Range™ (portable) | • Stepper motor-driven bellows    | • Integrated design<br>• No safety isolation box |
| <b>Maquet</b>   | Cardiosave Hybrid, Cardiosave Rescue       | • Pneumatic helium system         | • Modular design<br>• Safety isolation box       |

In China, the IABP market has historically been dominated by imported products from leading international manufacturers holding local registration certificates, and these imported systems have set the benchmark for technical specifications and clinical use over a long period. In 2025, three domestic manufacturers obtained approvals for their IABP systems, marking the beginning of meaningful domestic supply at the hospital level. Domestic IABP projects had entered R&D or type-testing before 2025, reflecting the difficulty of progressing from product development to regulatory approval and commercial supply. With advantages in cost, delivery capability and localized after-sales service, domestic brands are expected to gradually replace a portion of imported market share over time.

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| Company                      | Product                              | Drive Type                                                                        | System Design                                                                                         |
|------------------------------|--------------------------------------|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|
| <b>Life Cardio</b><br>(先健心康) | IAP-50                               | <ul style="list-style-type: none"> <li>Pneumatic helium system</li> </ul>         | <ul style="list-style-type: none"> <li>Modular design</li> <li>Safety isolation disk</li> </ul>       |
| <b>Novlead</b><br>(諾令生物)     | A100, A200                           | <ul style="list-style-type: none"> <li>Pneumatic helium system</li> </ul>         | <ul style="list-style-type: none"> <li>Modular design</li> <li>Safety isolation disk</li> </ul>       |
| <b>MERA</b>                  | HBP3                                 | <ul style="list-style-type: none"> <li>Electric-powered cylinder drive</li> </ul> | <ul style="list-style-type: none"> <li>Integrated design</li> <li>No safety isolation disk</li> </ul> |
| <b>Telelife</b><br>(通靈仿生)    | TL-IABP-100                          | <ul style="list-style-type: none"> <li>Stepper-motor drive</li> </ul>             | <ul style="list-style-type: none"> <li>Integrated design</li> <li>No safety isolation disk</li> </ul> |
| <b>Teleflex</b>              | IAP-0701, IAP-0601 (AC3)             | <ul style="list-style-type: none"> <li>Stepper-motor drive</li> </ul>             | <ul style="list-style-type: none"> <li>Integrated design</li> <li>No safety isolation disk</li> </ul> |
| <b>Maquet</b>                | Cardiosave Hybrid, Cardiosave Rescue | <ul style="list-style-type: none"> <li>Pneumatic helium system</li> </ul>         | <ul style="list-style-type: none"> <li>Modular design</li> <li>Safety isolation disk</li> </ul>       |

Source: NMPA (as of LPD), Frost & Sullivan Analysis

### Growth Drivers and Future Development Trends of IABP Market

Demand for IABP is supported by (i) a large and persistent burden of cardiogenic shock and acute decompensation in ICU and cath-lab settings, where rapid, readily deployable temporary support is often needed as a bridge to revascularization, surgery or escalation; (ii) the expanding volume and complexity of interventional and perioperative cardiovascular care, including complex and high-risk PCI, as supported by the 2021 ACC/AHA/SCAI coronary revascularization guideline which increases the need for procedural hemodynamic stabilization in a broader range of hospitals; and (iii) ongoing device iteration that improves portability, set-up efficiency, triggering performance and workflow integration, supporting replacement demand and wider adoption across routine critical-care pathways.

IABP is expected to evolve toward (i) clearer, more selective and protocol-driven use within the broader tMCS ladder, with more standardized initiation, monitoring and weaning across cath-lab, cardiac surgery and ICU workflows; (ii) continued innovation in vascular-protection and antithrombotic approaches, including exploration of NO-releasing or other coating technologies to reduce thrombosis and infection risks and potentially lower reliance on intensive systemic anticoagulation; and (iii) smarter pneumatic drive control and deeper integration with multi-modality critical care, including improved triggering/monitoring and better coordination with ventilation, ECMO and inhaled pulmonary vasodilators to support consistent use across a wider range of care settings.

### CHINA FeNO DIAGNOSTICS MARKET

FeNO is a quantitative, safe and easy-to-perform biomarker of airway inflammation. Elevated FeNO levels indicate eosinophilic airway inflammation and support the diagnosis and management of asthma, chronic cough, rhinitis and COPD, while low FeNO levels suggest non-eosinophilic chronic respiratory diseases. FeNO measurement is non-invasive, rapid, and can be performed with a single controlled exhalation, making it suitable for both specialist and broader clinical settings.

FeNO has been progressively incorporated into international and national respiratory guidelines. Technical standards, including ERS 2017 and ERS 2024, have standardized measurement procedures, reporting formats and reference values for adults and children, which support routine use of FeNO as an objective test in clinical decision-making. Clinical practice guidelines, including GINA 2026, BTS/NICE/SIGN 2024 and ATS 2021, recommend FeNO as an auxiliary test and, where available, a first-line test in suspected asthma, and support the use of FeNO to guide asthma treatment in selected patients. FeNO and nasal NO are also referenced in the assessment of upper-airway inflammatory diseases under IRS 2019.

### Major Indications for FeNO Diagnostics

FeNO diagnostics are primarily used in the management of COPD, asthma and broader airway-inflammation conditions, including chronic cough, allergic rhinitis and chronic rhinosinusitis. Across these indications, FeNO provides a non-invasive, rapid and repeatable biomarker of eosinophilic airway inflammation that supports diagnosis, phenotyping, treatment selection and longitudinal monitoring, and complements symptoms and lung-function testing in both hospital and outpatient settings. FeNO provides a non-invasive, rapid and repeatable assessment of eosinophilic airway inflammation and can support phenotyping and treatment monitoring. However, it is a complementary biomarker rather than a stand-alone diagnostic test, and results may be affected by factors such as smoking, infection, atopy and corticosteroid use. Spirometry, bronchodilator reversibility or provocation testing provide more direct assessment of

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## INDUSTRY OVERVIEW

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airflow limitation or variability, while blood eosinophils/IgE and imaging provide complementary systemic or structural information. Accordingly, these diagnostic approaches generally serve different and complementary clinical purposes.

**COPD.** In COPD, FeNO is typically higher in patients with asthma-like features or eosinophilia and correlates with blood and sputum eosinophil counts. It is therefore used as an adjunct marker to identify eosinophilic or overlap phenotypes, to select patients more likely to respond to inhaled corticosteroid-containing regimens and to support closer follow-up of higher-risk subgroups. Compared with spirometry and imaging, FeNO is more useful for identifying eosinophilic or overlap phenotypes and supporting ICS selection, rather than assessing airflow limitation or structural change. Compared with sputum eosinophils, it is easier to repeat, but in COPD it is mainly a supportive test used in selected patients. For details about COPD, see “— Global iNO Therapy Market — Major Indications for iNO Therapy — Chronic Obstructive Pulmonary Disease.”

**Asthma.** Asthma is a chronic inflammatory airway disease with variable airflow obstruction and recurrent symptoms such as wheeze, chest tightness and cough. FeNO has been recognized as a quantitative and easy-to-perform marker of eosinophilic airway inflammation and is recommended in clinical pathways for suspected asthma where available. China’s asthma population rose from 64.7 million in 2020 to 70.9 million in 2025. Prevalence is projected to reach 76.9 million in 2030 and 82.8 million in 2035. Compared with reversibility or provocation testing, FeNO is less important for confirming diagnosis but more useful for assessing type-2 inflammation, likely ICS responsiveness and anti-inflammatory control over time. Its strength lies in repeatability and treatment guidance.

**Airway Inflammation Diseases.** Airway inflammation is a common underlying problem in many long-term respiratory diseases, including asthma, chronic cough, allergic rhinitis, chronic rhinosinusitis (with or without nasal polyps) and certain subgroups of COPD. FeNO and eosinophil levels are therefore important, which indicates broad potential for using FeNO to characterize airway inflammation, evaluate the effect of anti-inflammatory treatment and monitor prognosis over time. In China, airway-inflammation prevalence increased from 446.1 million in 2020 to 470.6 million in 2025. It is projected to reach 493.9 million in 2030 and 514.5 million in 2035. Compared with blood eosinophils and IgE, FeNO is more airway-focused and more responsive to local eosinophilic inflammation. Compared with induced sputum, it is less detailed but much more practical for serial use, making it more useful for stratification, treatment monitoring and follow-up.

### China FeNO Diagnostic Device Market Size

Supported by a large chronic airway-disease patient pool, broader use scenarios, continued policy and guideline support, improving education and awareness, and the gradual shift of FeNO from hospital-based testing toward routine longitudinal monitoring and, over time, selected portable home-based chronic disease management, China’s FeNO market is expected to maintain strong long-term growth. The following chart depicts the historical and expected growth trajectory of China FeNO diagnostic device market from 2020 through 2035.

For FeNO, the historical market size was estimated principally based on sales revenue of relevant market participants. The forecast takes into account the underlying asthma and airway-inflammation patient populations, analyzer availability and adoption, testing penetration and testing frequency, utilization per installed analyzer, recurring test-consumable usage, expansion across relevant care settings and pricing trends. The underlying disease population represents a potential patient ceiling rather than the number of patients assumed to receive FeNO testing, and forecast growth therefore principally reflects increased testing adoption and frequency rather than epidemiological growth alone.

- Supported by a large chronic airway-disease patient pool, broader use scenarios, continued policy and guideline support, improving education and awareness, and the gradual shift of FeNO from hospital-based testing toward routine longitudinal monitoring and, over time, selected portable home-based chronic disease management, China’s FeNO market is expected to maintain strong long-term growth.
- China’s FeNO market is projected to expand from RMB 125.0 million in 2020 to RMB 226.7 million in 2025, 12.6% CAGR, reflecting a hospital-anchored adoption stage where FeNO is mainly offered through respiratory outpatient clinics and pulmonary function labs as an add-on test for airway inflammation assessment rather than as routine home monitoring.

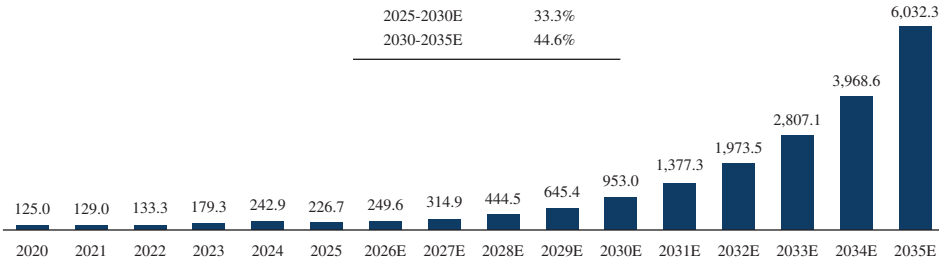
## INDUSTRY OVERVIEW

- From 2025 to 2030E, China’s FeNO diagnostic device market is forecast to increase from RMB226.7 million to RMB953.0 million, representing a CAGR of 33.3%, and further to RMB6,032.3 million by 2035E, representing a CAGR of 44.6% from 2030E. The forecast growth is principally driven by increased testing penetration and testing frequency rather than growth in the underlying disease population alone. China’s asthma prevalence is projected to increase from approximately 70.9 million in 2025 to 76.9 million in 2030E and 82.8 million in 2035E, while the broader airway-inflammation population is projected to increase from approximately 470.6 million to 493.9 million and 514.5 million, respectively. Against this large underlying pool, growth is expected to be supported by broader guideline-based use, clinical education and awareness, expansion of testing from specialist respiratory clinics and pulmonary-function laboratories into broader outpatient and primary-care settings, increased analyzer utilization and recurring test-consumable use, declining device and per-test costs, and, over time, selected portable and home-monitoring applications. The extent and timing of such expansion remain dependent on clinical acceptance, regulatory availability, affordability and payer or consumer uptake.

### China FeNO Therapy Market Size and Forecast, 2020-2035E

Unit: Million RMB  
At ex-factory price level

| Period     | CAGR  |
|------------|-------|
| 2020-2025  | 12.6% |
| 2025-2030E | 33.3% |
| 2030-2035E | 44.6% |



Source: Frost & Sullivan Analysis

### Competitive Landscape

In China, the FeNO diagnostic device market is supplied mainly by domestic manufacturers, with a small group of companies accounting for the majority of marketed products. Within this landscape, we have obtained registrations for seven marketed FeNO devices and detectors and rank among the leading domestic manufacturers. We are currently the only domestic player with an approved chemiluminescence-based FeNO analyzer, positioning our portfolio in both the high-precision segment and the mainstream electrochemical segment of the market.

### SOURCE OF INFORMATION

We commissioned Frost & Sullivan, an independent market research and consulting company, to conduct an analysis of, and to prepare a report on the global iNO therapy market, China IABP market and China FeNO diagnostics market for use in this document (the “F&S” Report). We have agreed to pay a fee of RMB830,000 to Frost & Sullivan in connection with the preparation of the F&S Report. We have extracted certain information from the F&S Report in this section and elsewhere in this document to provide our potential [REDACTED] with a more comprehensive presentation of the industries where we operate. In compiling and preparing the F&S Report, Frost & Sullivan adopted the following assumptions: (i) the social, economic and political conditions globally currently discussed will remain stable during the forecast period, (ii) government policies on medical devices in main markets globally will remain consistent during the forecast period, (iii) medical devices markets will be driven by the factors which are stated in this report in the forecast period. Except as otherwise noted, all of the data and forecasts contained in this section are derived from the F&S Report. The F&S Report has been prepared by Frost & Sullivan independently without any influence from us or other interested parties. Frost & Sullivan is an independent global consulting firm founded in 1961 in New York and its services include, among others, industry consulting, market strategic consulting and corporate training. Frost & Sullivan conducted (i) primary research, which involved discussing the status of the industry with certain leading industry participants, and interviews with industry experts on a best-effort basis to collect information in aiding in-depth analysis; and (ii) secondary research, which involved reviewing company reports, independent research reports and data based on its own research database.

Our Directors confirm that after taking reasonable care, there has been no adverse change in the market information since the date of the report prepared by Frost & Sullivan which may qualify, contradict or have an impact on the information set forth in this section in any material respect.