

Research on the Domestication and Standardization of Respiratory Medical Devices for Primary Healthcare Institutions

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Abstract

This study addresses the core challenges of high import dependency, poor scene adaptation, and high maintenance costs of respiratory medical devices in primary healthcare institutions in China. Through multidimensional surveys, technological development, and clinical verification, a comprehensive domestication and standardization system was established. A stratified sampling method was employed to survey 200 primary healthcare institutions across 10 provinces in eastern, central, and western China, with 1,200 valid questionnaires and 80 in-depth interviews. The study identified three-dimensional requirements in terms of environment (high-altitude pressure compensation and cold fog prevention), operation (simplified interface and voice guidance), and cost (procurement $\leq$ \$3,000 per unit, maintenance $\leq$ \$200 per year). Core components such as low-noise permanent magnet synchronous motors (noise 36 dB, cost reduced by 40%) and aging-resistant silicone (leakage rate 4.8%, lifespan over 6 months) were developed, along with environment-adaptive algorithms (92.1% effective in high-altitude treatment, 100% success rate in low-temperature fog prevention). A multicenter controlled trial involving 50 institutions and 400 COPD patients verified that the domestic devices had a failure rate of 5.0% (compared to 12.0% for imported devices) and reduced maintenance costs by 62.1% ($p < 0.05$). Ultimately, a three-tier standard system of “foundation – technology – evaluation” was constructed, proposing a weighted evaluation model with 40% for technical adaptability, 30% for cost adaptability, and 30% for maintenance adaptability. The research provides technical support and standard basis for the domestication of respiratory devices in primary healthcare institutions, contributing to the upgrade of grassroots medical equipment in “Healthy China 2030”.

Keywords: primary healthcare institutions, respiratory medical devices, domestication, adaptation technology, standard system, non-invasive ventilator, clinical verification

1. Introduction

1.1 Research Background and Problem Statement

Primary healthcare institutions (township health centers and community health service centers) in China undertake over 65% of the initial

diagnosis of respiratory diseases nationwide. However, the high import dependency and poor scene adaptation of respiratory medical devices have become the core bottlenecks restricting the quality of diagnosis and treatment. Market data shows that the import proportion of core devices such as non-invasive ventilators and ventilation masks in primary healthcare institutions reaches 62.3%. These devices, designed based on the physiological characteristics of Western populations, exhibit significant inadaptation in primary care settings. For example, the leakage rate of ventilation masks, due to insufficient facial contour matching, is as high as 28.7% (n=200, measured in primary healthcare institutions), directly leading to a pressure control accuracy deviation of over ± 2.0 hPa. The operation interface of non-invasive ventilators, on average, contains 14.2 physical buttons, and the independent operation qualification rate of primary healthcare staff is only 35.4%, 58.6 percentage points lower than that in tertiary hospitals. The contradictions in maintenance are even more prominent, with an average repair response cycle of 15.3 days for imported devices and an annual maintenance cost of \$5,218, which are 3.1 and 2.6 times the budget threshold of primary healthcare institutions, respectively.

Policy guidance provides clear support for solving the above problems. The “14th Five-Year Plan for the Development of Medical Equipment Industry” lists the “domestication of grassroots-adaptive medical equipment” as a key task and proposes the goal of increasing the market share of domestic medical devices in grassroots institutions to 50% by 2025. The “Healthy China 2030 Plan Outline” further clarifies the requirement to improve the standard system of grassroots medical equipment and break through the technical barriers of core components. Against this backdrop, conducting research on the scene adaptation technology and standardization of respiratory medical devices in primary healthcare institutions is not only a practical need to break the vicious cycle of “import dependency — poor adaptation — high cost” but also an inevitable choice for promoting the high-quality development of the medical equipment industry.

1.2 Research Significance

1.2.1 Clinical and Public Health Value

By improving technical adaptation and cost

optimization, this study directly enhances the accessibility of respiratory disease diagnosis and treatment in primary care. Clinical pre-experiments have shown that the leakage rate of the optimized domestic ventilation masks can be controlled below 4.8%, and the operation training time for non-invasive ventilators is reduced from 48 hours to 8 hours. The maintenance response cycle is compressed to within 48 hours, and the annual cost is reduced to \$1,980. Based on the 120 million patients with chronic obstructive pulmonary disease (COPD) in China, it is estimated that if grassroots healthcare institutions fully adopt domestically adapted devices, the average monthly visit frequency of patients can be reduced by 1.2 times, and the risk of readmission can be lowered by 21.7%, which has a synergistic effect with the clinical benefits of the Internet of Things management model.

1.2.2 Industrial and Technological Value

The study focuses on the domestication of core components, breaking through the “bottleneck” links of ventilator motors and mask silicone materials. The jointly developed low-noise permanent magnet synchronous motor reduces the noise level from 45 dB of imported products to 36 dB, with a failure rate of only 1.8% after continuous operation for 10,000 hours, and a cost reduction of 40% compared to imported components. The medical-grade aging-resistant silicone, after 1,000 hours of accelerated aging testing, maintains an elasticity rate of 82%, which is on par with ResMed’s similar products. The increase in the domestic controllability rate of core components has led to a 35.2% reduction in the overall procurement cost of domestic devices, providing technical support for domestic enterprises to enter the grassroots market and is expected to drive the growth of the related industrial chain value by over \$20 billion.

1.2.3 Theoretical and Standard Value

Current domestic and international research exhibits a significant “high-end orientation,” with over 90% of respiratory device studies focusing on the application scenarios of tertiary hospitals, and systematic research on the special needs of grassroots institutions accounting for less than 5%. This study constructs a complete framework of “need identification — technical breakthrough — standard construction — clinical verification” and proposes for the first

time a three-dimensional index system for grassroots adaptability evaluation, filling the theoretical gap in this field and providing a methodological reference for subsequent grassroots-oriented research on medical equipment.

2. Analysis of Grassroots Needs and Domestication Bottlenecks

2.1 Multidimensional Identification of Grassroots Scene Needs

A stratified sampling method was used to survey 200 primary healthcare institutions across 10 provinces in eastern, central, and western China, with 1,200 valid questionnaires and 80 in-depth interviews. Combined with clinical data, a three-dimensional need model of “environment — operation — cost” was constructed. In terms of environmental adaptation, in medical institutions located in plateau areas (altitude $\geq 2,000$ meters), 85.3% reported insufficient pressure compensation of imported devices, resulting in a treatment effectiveness rate of only 58.6%. In cold areas

(below -10°C), 72.1% of the devices experienced fogging in the airway, increasing the airflow resistance by 35%. In humid areas, the equipment circuit corrosion failure rate reached 30.7%, which is 2.3 times higher than that in dry areas.

The operational adaptation needs show a significant “simplification tendency.” Primary healthcare staff, on average, receive only 18.2 hours of device training and have an acceptance rate of less than 20% for operation interfaces with more than 8 buttons. 60.4% of respondents indicated that “lack of Chinese voice guidance” is the main cause of operational errors, and dialect needs cover six major languages, including Cantonese and Sichuanese. In terms of cost, the average annual maintenance budget for a single ventilator in primary healthcare institutions is only \$980, which is only 18.8% of the actual expenditure of imported devices. When the replacement cost of vulnerable components exceeds 15% of the total equipment price, it becomes unbearable.

Table 1.

Environment Type	Reported Issue	Proportion	Impact
Plateau regions ($\geq 2,000$ m a.s.l.)	Insufficient pressure compensation of imported equipment	85.3%	Treatment efficacy drops to only 58.6%
Cold regions (below -10°C)	Fogging in device tubing	72.1%	Airflow resistance increases by 35%
Humid regions	Circuit corrosion failures	30.7%	2.3× higher than in dry regions

2.2 Core Bottlenecks of Domestication Adaptation

The technical barriers of core components are the primary obstacles. The market for low-noise ventilator motors is monopolized by companies such as Germany’s Bosch. Domestic motors have an average noise level 8 dB higher than imported ones, with power consumption exceeding standards by 18.5% and a failure rate of 12.3% after continuous operation for 5,000 hours. In the field of mask silicone materials, the medical-grade certification pass rate is only 45%, and the elasticity retention rate after 1,000 hours of aging is 25 percentage points lower than that of imported materials. The control chip sector is also dominated by imports, with domestic chips processing data 20% slower and having a failure rate of 5.2% in environments ranging from -10°C to 40°C , which is insufficient to support the

implementation of environment-adaptive functions. (Kabir, A. S. M. S. H., Khan, M. A. H., & Bhuiyan, M. A. H., 2020)

The lack of scene adaptation technology exacerbates the supply-demand contradiction. Domestic enterprises mostly adopt the “benchmark imitation” model. Over 90% of domestic ventilators have not developed plateau pressure compensation algorithms. In clinical tests conducted in Lijiang, Yunnan (altitude 2,400 meters), the treatment effectiveness rate dropped by 43.2% compared to plain areas. Only 12% of products have low-temperature fog prevention functions, and in the winter of Hulunbuir, Inner Mongolia, the airway blockage rate reached 68.3%. The lag in maintenance technology results in device failure diagnosis relying on external experts, with an average

repair response time of 72.5 hours, which is twice the grassroots threshold.

The absence of a standard system constitutes a systemic obstacle. The existing standards do not cover the special requirements of grassroots scenarios: environmental adaptability indicators do not include extreme ranges of altitude, temperature, and humidity; operational convenience lacks quantitative evaluation; and cost adaptability does not include maintenance cost control requirements. The lack of standards leads to enterprises' R&D direction deviating from actual needs. In 2023, only 3 out of 15 newly launched domestic grassroots ventilators passed the multi-scene adaptability test, with a compliance rate of only 20%.

3. Development and Verification of Domestication Adaptation Technology Path

3.1 Autonomous Development of Core Components

In the development of ventilator motors, a "distributed winding + double-layer sound insulation structure" design was adopted. The copper loss of the stator winding was reduced by 15%, the torque ripple was reduced by 22% through the optimization of the rotor magnet arrangement, and the combination of an inner layer of sound-absorbing cotton and an outer layer of aluminum alloy cover in the shell achieved a noise reduction of 9 dB. After testing by the National Medical Device Testing Center, the motor's noise level was 36 dB, power consumption was 35 W, and the failure rate after continuous operation for 10,000 hours was 1.8%. The core parameters are close to those of Philips' similar products, with a cost of only 60% of the imported ones.

Table 2.

Parameter Description	Specific Value / Condition
Reduction in stator-winding copper losses	15%
Torque-ripple reduction	22%
Noise-attenuation performance	9 dB
Motor sound-pressure level	36 dB
Motor power consumption	35 W
Failure rate after 10,000 h continuous operation	1.8%
Comparison of core parameters with Philips equivalent	On par
Cost ratio vs. Philips equivalent	60%

The optimization of mask silicone material was achieved through a three-step process of "raw material selection — process improvement — performance verification." Three candidate materials with tensile strength ≥ 5 MPa and tear strength ≥ 20 kN/m were selected from 10 types of medical silicone raw materials. The material's cross-linking density was increased by 30% through low-temperature vulcanization at 120°C and surface plasma modification. Accelerated aging tests (1,000 hours, 70°C, 95% RH) showed that the elasticity retention rate of the optimized silicone reached 82%, with biological compatibility meeting ISO 10993-1 standards. The mask leakage rate was reduced to 4.8%, and the service life was extended to over 6 months.

The customized development of control chips focused on stability and adaptability. In collaboration with domestic chip enterprises, a

dedicated chip meeting IEC 60601-1 standards was developed, reducing the high and low-temperature failure rate to below 1.0% through a dual-core backup design. The lightweight pressure control algorithm developed increased data processing speed by 25%, and in combination with an altimeter (measurement range 0-5,000 meters, accuracy ± 10 meters), it achieved a precise pressure compensation of 12.5% for every 1,000 meters of altitude increase.

3.2 Integration Innovation of Scene-Adaptive Technology

The environment-adaptive system consists of three major algorithm modules: The plateau pressure compensation module increased the treatment effectiveness rate from 60.3% to 92.1% in clinical tests in Lijiang, Yunnan. The low-temperature fog prevention module

stabilized the airway temperature at 18°C through a carbon fiber heating wire (power 5 W), achieving a fog prevention success rate of 100% in -25°C environments. The energy consumption adaptive module can automatically switch operating modes based on battery power, maintaining basic respiratory support functions for over 8 hours when the power is ≤20%, adapting to unstable power supply environments in grassroots areas.

The optimization of the human-machine interaction system is centered on “minimalist operation + intelligent guidance.” The physical buttons were streamlined to 8, with core parameters displayed in 16pt large font, and a Chinese voice guidance module (clarity 95.3%) covering the entire process of startup, parameter setting, and fault troubleshooting, as well as providing options for three dialects, including Cantonese and Sichuanese. In tests conducted in Guangdong and Sichuan grassroots medical institutions, the independent operation qualification rate of medical staff increased from 35.4% to 95.2%, and the operation time was reduced from 15 minutes to 4.8 minutes.

Lightweight maintenance technology significantly improves service efficiency. The device is equipped with 20 built-in self-diagnosis programs for common faults, with an identification accuracy rate of 95.6%. Fault types are indicated through both indicator lights and voice prompts, along with visual repair guidance. The mask adopts a snap-on design, with a replacement time of ≤90 seconds. The integrated 4G module of the remote maintenance platform enables real-time transmission of operating data and fault warnings, reducing the maintenance response time from 72.5 hours to within 48 hours and reducing maintenance costs by 62%.

3.3 Multidimensional Technology Verification

Laboratory performance verification was completed at the National Medical Device Testing Center of the National Medical Products Administration, with 20 core indicators of the

domestic adaptation devices (G3B20A non-invasive ventilator, N5B ventilation mask) being tested. The results showed that the pressure control accuracy of the ventilator was ±0.4 hPa, the failure rate in extreme environments (-10°C to 40°C) was 3.0%, the mask leakage rate was 4.8%, the elasticity retention rate after aging was 82%, and the electromagnetic compatibility met the Level 3 requirements of YY 0505-2012. All indicators exceeded the preset standards, with key performance improvements of 12%-18% compared to imported similar products. (Jayawardena, J. A. R. P., & Kabir, A. S. M. S. H., 2019)

The grassroots clinical verification was designed as a multicenter, controlled trial, selecting 50 primary healthcare institutions in three provinces: Yunnan (plateau), Inner Mongolia (cold), and Guangdong (humid). The institutions were divided into a test group (domestic devices) and a control group (imported devices) in a 1:1 ratio, with 200 COPD patients included in each group for a verification period of 3 months. The treatment compliance of the test group reached 92.3%, 11.2 percentage points higher than that of the control group. The device failure rate was 5.0%, only 41.7% of the control group (12.0%), and the annual maintenance cost was \$1,980, a 62.1% reduction compared to the control group, with statistically significant differences between the groups ($p < 0.05$).

Based on clinical feedback, technical iterations were completed: The device weight was reduced from 5 kg to 3.5 kg using lightweight aluminum alloy materials; a USB charging interface was added to adapt to general grassroots devices; and the algorithm response speed was optimized from 2 seconds to 1 second. After these iterations, the user satisfaction in the second batch of 30 grassroots hospitals increased to 95.0%, and the failure rate dropped to 3.0%, achieving the expected optimization goals.

Table 3.

Validation Index	Domestic Equipment Data
Ventilator pressure-control accuracy	±0.4 hPa
Failure rate in extreme environments (-10 °C to 40 °C)	3.0 %
Mask air-leak rate	4.8 %

Elastic retention rate of mask after aging	82 %
Electromagnetic compatibility	Meets YY 0505-2012 Level 3
Treatment compliance	92.3 %
Device failure rate	5.0 %
Annual O&M cost	RMB 1,980
User satisfaction	95.0 %
Failure rate	3.0 %

4. Construction of Domestication Adaptation Standard System

4.1 Framework Design of Standard System

A three-tier standard system of “basic standards — technical standards — evaluation standards” was constructed. The basic standards include “Terminology and Classification of Grassroots Respiratory Medical Devices” and “General Safety Requirements,” defining core terms such as “grassroots scene adaptability” and clarifying general requirements for electrical safety (GB 9706.1-2020 Class I, BF type) and electromagnetic compatibility (YY 0505-2012). The technical standards cover the specific requirements for five types of products, including non-invasive ventilators and ventilation masks, which are the core carriers of the system. The evaluation standards include “Adaptation Evaluation Method” and “Certification Process,” regulating the testing and certification links.

The standard formulation strictly follows three bases: In terms of policy, it connects with the grassroots requirements of the “14th Five-Year Plan for the Development of Medical Equipment Industry”; in terms of technology, it integrates domestication technical parameters with GB 9706 series and ISO 10993 standards; and in terms of demand, it converts the grassroots environment, operation, and cost requirements based on the survey data from 10 provinces into quantitative indicators to ensure the scientificity and practicality of the standards.

4.2 Quantitative Setting of Core Technical Indicators

Performance indicators focus on core functions and stability: The noise of non-invasive ventilators should be ≤ 38 dB, with a pressure range of 4-20 hPa (accuracy ± 0.5 hPa), an altitude adaptation range of 0-5,000 meters (compensation accuracy $\pm 10\%$), and a failure rate of $\leq 2\%$ after continuous operation for 10,000 hours. The leakage rate of ventilation masks

should be $\leq 5\%$, with a wearing comfort VAS score of ≥ 90 points and a service life of ≥ 6 months. The breathing circuit should not be blocked after 180° bending for 100 times and should maintain a temperature of $\geq 15^\circ\text{C}$ in -10°C environments.

Scene adaptation indicators reflect grassroots specificity: Environmental adaptation requires a normal operation rate of $\geq 95\%$ under conditions of altitude 0-5,000 meters, temperature -10°C to 40°C , and humidity 15%-90% RH. Operational adaptation specifies that the operation steps should be ≤ 5 , with a qualified rate of $\geq 95\%$ for medical staff after training, and voice guidance should support Chinese and at least two dialects. Cost adaptation stipulates that the procurement cost of a single non-invasive ventilator should be $\leq \$3,000$, the annual maintenance cost should be $\leq \$2,000$, and the replacement cost of vulnerable components should be $\leq 5\%$ of the total equipment price.

Safety and compliance indicators strengthen risk control: The grounding resistance of electrical safety should be $\leq 0.1\Omega$, and the patient leakage current should be $\leq 50\mu\text{A}$. Software safety should meet IEC 62304 Class B requirements, with no high-risk vulnerabilities. Data storage should comply with the “Personal Information Protection Law,” with encrypted retention for ≥ 3 years, and the risk control requirements should be consistent with those of similar products.

4.3 Adaptation Evaluation Model and Process

The evaluation model uses a weighted scoring method, constructed from three dimensions: technical adaptability (40%), cost adaptability (30%), and maintenance adaptability (30%). Technical adaptability includes core component performance (15%), environmental adaptability (10%), and operational convenience (15%). Cost adaptability covers procurement cost (15%), maintenance cost (10%), and energy consumption cost (5%). Maintenance

adaptability includes fault diagnosis capability (10%), component replacement convenience (10%), and remote support capability (10%).

(Sheehan, J. R. F., 2017)

Quantitative evaluation uses a 10-point scale, with clear scoring rules for key indicators:

Table 4.

Item	Scoring Rule	Points Awarded
Motor noise	≤ 38 dB	10 points
	38–45 dB	8 points
	> 45 dB	5 points
Mask leak rate	≤ 5 %	10 points
	5 %–10 %	8 points
	> 10 %	5 points
Procurement cost	≤ RMB 30 k	10 points
	RMB 30–40 k	8 points
	> RMB 40 k	5 points

The evaluation process is divided into three stages: Enterprise self-testing requires submission of core component test data and scene verification records; third-party testing is conducted by national-level institutions for performance testing and scene verification, issuing test reports; comprehensive evaluation is carried out by industry experts who calculate scores based on self-testing and test results, and issue an “Adaptation Evaluation Certificate” valid for 3 years, which requires re-evaluation upon expiration.

5. Conclusions and Future Work

5.1 Main Research Conclusions

This study systematically identified the core needs of grassroots respiratory medical devices: Environmental adaptation needs to address issues such as insufficient plateau pressure and fogging in cold areas, operational adaptation needs to simplify processes and enhance voice guidance, and cost adaptation needs to control procurement and maintenance expenditures. Based on these needs, significant breakthroughs were achieved in the development of core components and scene-adaptive technologies: The performance of core components such as low-noise motors and aging-resistant silicone is close to the international advanced level. The environment-adaptive algorithms ensure a normal operation rate of 95% for devices under extreme conditions, and the optimization of human-machine interaction increases the

operation qualification rate by 60 percentage points.

The constructed three-tier standard system fills the industry gap. Its “technology — scene — safety” three-dimensional indicators and weighted evaluation model provide a unified basis for enterprise R&D, device testing, and grassroots procurement. Laboratory and clinical verifications have proven that the comprehensive performance of domesticated adaptation devices is superior to that of imported products, with a 35.2% reduction in procurement costs and a 62.1% reduction in maintenance costs, making them ready for large-scale promotion in grassroots areas.

5.2 Research Limitations and Future Directions

The study has three limitations: The survey did not fully cover extreme environment areas such as Tibet and Xinjiang, and the inclusion of special scene needs is not comprehensive enough; the technology verification period was 3 months, and long-term stability data for 1-2 years still need to be accumulated; the standard system does not include emerging needs such as the integration of AI technology. Future work will focus on two aspects: First, supplementing surveys in extreme environments to expand the scope of technical adaptation and conducting a 5-year long-term clinical follow-up; second, establishing a dynamic update mechanism for standards to incorporate new technical indicators such as AI respiratory monitoring and

5G remote maintenance, and promoting the alignment of standards with the international IEC and ISO systems.

Policy recommendations include incorporating “well-adapted” devices into the priority procurement directory for grassroots institutions, with a 15% financial subsidy. In the industrial sector, a collaborative innovation platform involving “enterprises + universities + medical institutions” should be established to continuously break through core technologies. In the clinical sector, device operation training should be strengthened to fully leverage the clinical value of domesticated devices, ultimately achieving the goal of 100% domestication and scene adaptation of grassroots respiratory devices.

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