

ISO 17510:2015 Carbon Dioxide Rebreathing Tester

Professional Technical Datasheet (Enhanced Version)



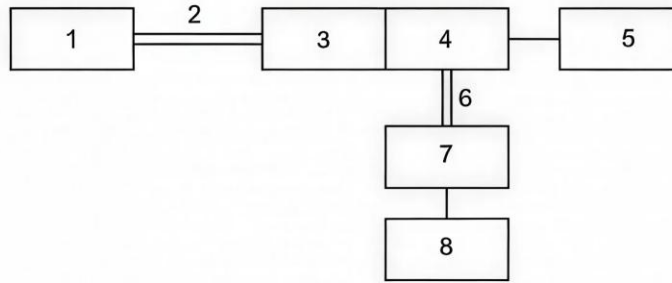
Model: KP-Y671F | Compliant with ISO 17510:2015 Annex F & YY/T 0671-2021

Product Overview

The KingPo ISO 17510:2015 Carbon Dioxide Rebreathing Tester (Model KP-Y671F) is a specialized medical testing system designed to evaluate the effectiveness of exhaust ports in sleep apnoea breathing therapy masks and patient interfaces. It accurately simulates realistic human breathing conditions to measure carbon dioxide rebreathing levels under both normal and single-fault conditions in accordance with ISO 17510:2015 Annex F.

This tester provides medical device manufacturers, quality assurance teams, and third-party certification laboratories with a reliable, repeatable solution to verify patient safety by ensuring minimal CO₂ rebreathing, thereby reducing the risk of hypercapnia during CPAP/BiPAP therapy. The system features a 7-inch Weintek color touchscreen, advanced PLC control, high-precision infrared CO₂ analyzer, and anatomically accurate PVC head mold with built-in 200 mL dead space.

Figure F.1 illustrates the test setup for the determination of CO₂ REBREATHING testing.



Key

1	flow source	5	CO ₂ monitor
2	1,9 m ± 0,15 m BREATHING TUBE	6	dead space of 140 ml ± 5 ml
3	MASK and, if applicable, connecting element	7	test lung simulator (driving ventilator + breathing simulator)
4	simulated PATIENT head	8	CO ₂ constant flow source

NOTE 1 A lung chamber volume of approximately 10 l, with an active mixing fan, is recommended to ensure satisfactory mixing.

NOTE 2 Adapted from Reference. [X]

Key Advantages

- **High-Precision Infrared CO₂ Analysis**

Engineering: Infrared CO₂ analyzer with built-in sampling pump (1–100 L/min adjustable) delivers fast, stable, and highly repeatable gas concentration readings with excellent accuracy.

Benefit: Enables precise quantification of rebreathing levels, ensuring masks meet strict patient-safety thresholds and reducing regulatory approval risk.

- **Realistic Breathing Simulation**

Engineering: Programmable sinusoidal waveform generator delivers 15 breaths/min, 0.5 L tidal volume, and 1:2 inspiratory-to-expiratory ratio with precise PLC control.

Benefit: Faithfully replicates human respiratory physiology for clinically relevant and ISO-compliant test results.

- **Anatomically Accurate PVC Head Mold**

Engineering: Quick-install breathing pipe with 200 mL built-in dead space accurately simulates human upper airway dead space volume.

Benefit: Ensures realistic gas mixing and rebreathing dynamics, critical for accurate exhaust-port performance evaluation.

- **Intuitive 7-Inch Touchscreen PLC Control**

Engineering: Weintek 7-inch color touchscreen with advanced PLC provides real-time monitoring, programmable test cycles (0–99,999 s), and automatic data logging.

Benefit: Dramatically reduces operator training time and testing cycle duration while ensuring full traceability for regulatory audits.

- **Comprehensive Pressure & Fault Simulation**

Engineering: Adjustable positive airway pressure (0–30 kPa) with high-accuracy differential pressure sensors (0–2000 Pa, ±1% F.S.) for both normal and single-fault condition testing.

Benefit: Enables complete ISO 17510:2015 Annex F compliance testing in a single platform, covering normal operation and blocked-tube fault scenarios.

Technical Specifications

Performance & Breathing Simulation

Parameter	Specification	Notes / Method
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Breathing Rate	15 breaths/min	Adjustable sinusoidal waveform
Tidal Volume	0.5 L	Standard adult simulation
Breathing Ratio (I:E)	1:2	Inspiratory : Expiratory
Waveform	Sinusoidal	Physiologically realistic
Test Duration	0–99,999 seconds	Programmable via touchscreen

CO₂ Analysis & Gas System

Parameter	Specification	Notes / Method
CO ₂ Analyzer	Infrared detection	High-precision with built-in pump
Sampling Flow Rate	1–100 L/min (adjustable)	Integrated sampling pump 0–150 L/min
Gas Supply	High-purity CO ₂ cylinder + compressed air	300 L/min @ 0.6 MPa required
Dead Space Volume	200 mL (built-in)	PVC head mold simulation

Pressure & Mechanical System

Parameter	Specification	Notes / Method
Positive Airway Pressure	0–30 kPa (adjustable)	Normal & single-fault conditions
Differential Pressure Range	0–2000 Pa ($\pm 1\%$ F.S.)	Real-time monitoring
Head Mold Material	PVC with quick-install pipe	Anatomically accurate
Power Supply	AC 220 V, 50 Hz, 1.5 kW	Standard laboratory power

Testing Principle & Acceptance Criteria

The CO₂ Rebreathing Tester quantifies the effectiveness of exhaust ports in sleep apnoea masks by simulating realistic breathing and measuring re-inhaled carbon dioxide. A breathing simulator delivers CO₂-enriched gas through the PVC head mold under regulated positive airway pressure. The infrared analyzer continuously records CO₂ levels inside the mask during normal operation and single-fault conditions (e.g., blocked breathing tube).

ISO 17510:2015 Annex F Acceptance Criteria

- Normal Condition: Relative CO₂ increase shall not exceed 20% when tested at the minimum rated pressure and at 5 hPa (and 10 hPa where applicable).
- Single-Fault Condition: Relative CO₂ increase shall not exceed 60% when tested with blockage of the breathing tube (equipment-end open to atmosphere).

Fully compliant with ISO 17510:2015 Annex F and YY/T 0671-2021 for carbon dioxide rebreathing testing of sleep apnoea masks and patient interfaces.

Best Practices for Accurate Testing

- Calibrate the infrared CO₂ analyzer and differential pressure sensors immediately before each test series using certified reference standards.
- Verify that the test mask is securely and leak-free fitted onto the PVC head mold with the breathing circuit properly connected.
- Confirm that all breathing simulation parameters (rate, tidal volume, waveform, pressure) exactly match ISO 17510:2015 Annex F requirements.
- Always use clean, dry compressed air and the supplied high-purity CO₂ source to prevent contamination or measurement drift.
- Log complete test data—including full CO₂ concentration curves, pressure profiles, fault conditions, and timestamps—for full traceability and regulatory audit readiness.

Primary Applications & Business Value

- Sleep Apnoea Mask Manufacturers — Comprehensive CO₂ rebreathing validation for nasal, full-face, hybrid, and pediatric masks
- Positive Airway Pressure Device Producers — Full interface compatibility and performance testing per ISO 17510:2015
- Medical Device Certification Laboratories — Independent type approval and regulatory compliance verification
- R&D and Product Development Teams — Rapid iteration and performance benchmarking of new mask designs

By delivering reliable, repeatable test data, the system helps companies accelerate product certification, enhance overall device performance, and build stronger confidence among clinicians and patients worldwide.

Model & Compliance

Model Code	Description	Standard Configuration
KP-Y671F	ISO 17510 CO ₂ Rebreathing Tester	Main unit + 7" touchscreen + head mold + CO ₂ cylinder + factory calibration

The CO₂ Rebreathing Tester is engineered and manufactured in strict accordance with ISO 17510:2015 Annex F. Each unit ships with a traceable factory calibration certificate. Optional ISO/IEC 17025 third-party accreditation is available upon request.

Manufactured under ISO 9001 and ISO 17025 certified quality management systems with responsive global technical support.

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