

AirwayMedix
SMARTER CARE

Professional Medical
Device Solution

CUFFIX

Automated Cuff Pressure
Regulation and
Measurement

Airway Medix S.A. • 2026



AGENDA

Cuff pressure in ICU settings

Ventilator-associated pneumonia

Introducing Cuffix

Cuffix application areas

Complete solution

Cuff pressure management

Market differentiation

Global market opportunity

Regulatory & compliance

CUFF PRESSURE IN ICU SETTINGS

Critical care affects **millions of patients worldwide** daily. Mechanical ventilation is a cornerstone of ICU care but **introduces significant risks if not properly managed** – particularly around endotracheal tube cuff pressure.

CURRENT CHALLENGE

Manual cuff pressure monitoring fails to detect fluctuations

- **60-80%** of patients exhibit abnormal pressures¹
- **Only 28%** maintain safe 20-30 cm H₂O range¹

CLINICAL RISK

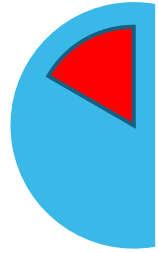
- Over-inflation (>30 cm H₂O): tracheal stenosis, necrosis, rupture²
- Under-inflation (<20 cm H₂O): aspiration risk, bacterial leakage³

MARKET SCALE

- **20M** ventilator days annually (major markets)⁴
- Expected to **DOUBLE** over next decade⁴



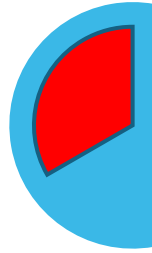
VENTILATOR-ASSOCIATED PNEUMONIA



VAP Epidemiology

9-27% of mechanically ventilated patients^{5,6}

Most common ICU-acquired infection⁶

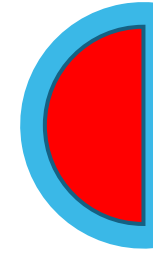


Impact

Mortality:
20-50%⁷

Cost per case:
€10,000-40,000⁸

ICU stay:
+6,1 days additional⁹



Risk Factors

Mechanical ventilation^{5,6}

Prolonged intubation^{5,6}

Improper cuff pressure management¹

INTRODUCING CUFFIX

Cuffix is designed to indicate and regulate the intracuff pressure of endotracheal tubes, tracheotomy tubes using passive control.



Scan to view IFU



KEY FEATURES

- ✓ Continuous 24/7 monitoring and automated regulation
- ✓ Maintains 20-30 cm H₂O range automatically
- ✓ 3 cm H₂O precision measurement
- ✓ Single-patient use (no cross-contamination)
- ✓ Color-coded LED indicator
- ✓ Up to 10 days operation, battery-powered device
- ✓ Minimal staff training

CUFFIX APPLICATION AREAS




ICU & Critical Care

VAP prevention in
mechanically ventilated
patients with evidence-
based protocols


**Anesthesiology
Departments**

Pre-operative and post-
operative management
and patient recovery
support


**Post-operative
recovery**

Post-operative recovery
and chronic disease
management for patient
independence

COMPLETE SOLUTION

THE SOLUTION: CUFFIX

FIRST automated continuous cuff pressure device. **ONLY** integrated measurement + regulation solution.

PATIENT SAFETY	CLINICAL EVIDENCE	ECONOMIC VALUE	OPERATIONAL	REGULATORY
✓ Helps to prevent tracheal injury through continuous control² ✓ Helps to eliminate dangerous pressure fluctuations² ✓ Helps to support VAP prevention bundles^{11,12}	✓ Maintains stable pressures¹⁰ ✓ Reduces pressure variability vs. manual monitoring¹⁰	✓ €5,000-20,000 saved per prevented VAP⁸ ✓ Staff time savings ✓ Reduces equipment costs	✓ Minimal training required ✓ Seamless workflow integration ✓ Single-use simplicity ✓ Battery-powered	✓ CE MDR approved ✓ ISO 13485:2016 certified

CUFF PRESSURE MANAGEMENT



AUTOMATED CUFF PRESSURE CONTROL



- Maintains stable pressures: 25.3 ± 4.2 cm H₂O¹⁰



- Manual control: highly variable 58.7 ± 21.1 cm H₂O¹⁰



VAP PREVENTION OUTCOMES



VAP prevention bundles with optimal cuff pressure control are associated with:

- 33-51% VAP reduction^{11,12}
- Reduced tracheal injury¹¹
- Shorter mechanical ventilation¹¹

Note: this evidence is based on peer-reviewed literature on automated cuff pressure management, not specific Cuffix clinical trial data.

MARKET DIFFERENTIATION



Automated endotracheal tube cuff pressure regulation and measurement solution



Innovative design based on clinical evidence



Simple-to-use for ICU nursing staff with minimal training requirements



Comprehensive support with staff training materials



Full regulatory compliance (CE MDR, ISO 13485)

GLOBAL MARKET OPPORTUNITY



Europe: 17,000+ hospitals with
~300,000 ICU beds¹³ • VAP incidence
19,4%¹³

North America: 6,000+ hospitals¹⁵ •
Highest VAP prevention awareness

Asia-Pacific: Rapid ICU expansion¹⁵

- **20M** ventilator days annually (major markets)⁴
- Expected to **DOUBLE** over next decade⁴

- HAI prevention mandates¹⁶ • VAP prevention as quality metric¹⁶ • Aging populations • Staff shortages driving automation

REGULATORY & COMPLIANCE

Medical Device Classification

Single use, non-sterile class I active device, applicable across ICU, anesthesia, and home care settings

ISO 13485:2016 Quality System

International quality management certification ensures safety and efficacy

CE MDR Compliance

European Union Regulation 2017/745 compliance established, pathway for other regions

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