*A **NEW** direction for **subglottic secretion** management*

SIMEX

The **SIMEX Subglottic Aspiration System**, ***cuff* M** and ***cuff* S** are the most advanced solution for the aspiration of subglottic secretion, featuring all new state-of-the-art **"Intermittent"** mode of therapy

Endotracheal tube with special suction lumen
Subglottic secretion
Tracheal tube with special suction lumen
Subglottic secretion is removed via the SIMEX *cuff* M or *cuff* S pump with the convenience of highly customized intermittent settings
OK
SIMEX
Medizintechnik
GmbH
cuff M

SIMEX brings together advanced engineering and the latest scientific research to provide the most advanced technology available for the effective management of subglottic secretions. Featuring simple to use, fully customizable intermittent suction that will change the way you manage subglottic aspiration in the ICU and acute care settings.

The **SIMEX *cuff* M and *cuff* S** are the only suction pumps designed and indicated for intermittent aspiration of subglottic secretions.

The **SIMEX Subglottic Aspiration System models *cuff* M and *cuff* S** are indicated for vacuum suction, extraction, aspiration and removal of surgical fluids, tissue (including bone), bodily fluids or infectious materials from patient's airway or respiratory system, either during surgery or at the patient's bedside. Generally, the **SIMEX Subglottic Aspiration System** is intended for removing subglottic secretions from the patient's airway above the endotracheal or tracheal cuff using intermittent suction when used in ICU and acute care settings where the duration of mechanical ventilation is limited to maximum of 4 weeks.

Features

- Allows effective removal of secretions from the subglottic region
- Used in conjunction with specially designed subglottic endotracheal and tracheal tubes with special suction lumens which have been proven effective in the management of subglottic secretion
- Vacuum pressure and ON/OFF time settings customizable to patient needs
- Vacuum pressure range can be digitally set from -20 to -300 mbar (10 mbar increments)
- Customizable ON/OFF times
  - Intermittent aspiration (ON) time can be set from 1-60 seconds
  - Intermittent aspiration (OFF) time can be set from 1-60 minutes
- AARC recommended pressure guidelines for intermittent aspiration for adult population are between -106 to -200 mbar (-80 to -150 mmHg)[15], the same pressure guidelines are recommended by endotracheal and tracheal tube manufacturers and the same pressures for adult population are recommended for use with ***cuff* M** and ***cuff* S**
- Safety alarm features for full canister and for low or fully discharged battery
- Simple, safe and easy to use
- Virtually silent operation (35dBA)
- Simple and uncomplicated menu control (color coded display)
- Disposable secretion container with integrated bacterial filter and gelling agent

Benefits

- Intermittent aspiration reduces the risk of injury due to drying of mucous membrane[6-7]
- Fully customizable to each patient's needs
- Increased patient comfort during aspiration process[20]
- Minimized maceration of surrounding tissue due to reduction of secretion leakage[20]
- Decreased need for frequent tracheal dressing changes due to reduction of secretion leakage[20]
- Self-contained collection canisters help prevent cross-contamination and minimize incidence of infection

Why use the *cuff* M or the *cuff* S pumps?

- The ***cuff* M** and ***cuff* S** are the only subglottic aspiration systems designed and indicated for intermittent aspiration of subglottic secretions.
- The ***cuff* M** and ***cuff* S** are the only suction pumps indicated for use with specially designed endotracheal or tracheal tubes with a separate dorsal suction lumen that opens directly above the ballooned cuff of the tube.
- Predominance of new research indicates that continuous aspiration of subglottic fluids can greatly reduce the incidence of ventilator-associated pneumonia (VAP) but that intermittent aspiration is more successful and reduces the risk of injury due to drying of the mucous membranes.[1,6-7] The benefits of reducing incidence of VAP in acute care settings is known, but long term incidence of VAP or reduction of mortality is not known at this time.
- New clinical experience in Europe has demonstrated the efficacy of intermittent subglottic aspiration with the ***cuff* M** and ***cuff* S**.[20]

VAP Facts

Ventilator-associated pneumonia (VAP) is the second most common nosocomial infection in the United States and results in both negative patient outcomes and increased healthcare costs[1]

- VAP is estimated to occur in 9-25% of all ICU patients alone[2-4]
- VAP is a costly complication of hospitalization that lengthens ICU and hospital stay and increases morbidity and mortality[5]
- Mortality that is directly attributable to VAP is estimated to be as high as 27%[10, 13-14]
- VAP is associated with more than $40,000 in increased hospital costs per patient and may be higher in certain types of patient care units[5]
- Current commonly used modalities of treatment involve recumbent positioning, oral hygiene, and some form of aspiration typically performed by nurses through use of a simple syringe and in some facilities by nurses attaching the patient's tracheal or endotracheal tube suction port to either wall suction regulators or portable (multi-purpose) suction devices[6-11]
- Emerging research indicates that aspiration of subglottic secretions and specifically the intermittent aspiration of subglottic secretions is extremely helpful in the reduction of the incidence of VAP[6-7,10,12,16-19]

Dr. med. Markus Wolf
Senior Physician Weaning Station, Department of Pneumology and Intensive Care
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"In our hospital in Hamburg Germany, we have had great success in the ICU using endotracheal tubes with a special suction lumen, along with the SIMEX *cuff* S subglottic aspiration system. During the past 21 months, over 250 patients have been treated successfully with no complications. In fact based on results of the past 21 months, this modality has become a standard of care for all patients admitted to our medical ICU and helped to decrease the average length of stay of patients on long term mechanical ventilation."

"In our facility in Nuremburg Germany, our standard of care to remove subglottic secretion was using a simple syringe or just a suction catheter. Four years ago we started evaluating a new aspiration device, the SIMEX *cuff* S and *cuff* M, used in conjunction with tracheal tubes with a special suction port. The results of this evaluation was so successful that the use of the *cuff* S or *cuff* M along with these specialized tracheal tubes is now a standard of care in our institution."

Helmut Fendler
"Innovator of original concept for cuff M/S"
Stoma Therapist, Certified RN,
GesundheitsManager GmbH, Nuremburg, Germany

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20 Data on file

SIMEX
Subglottic Aspiration System

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Technical Detail	SIMEX *cuff* S	SIMEX *cuff* M
Overall aspiration capacity	max 8 liters/min	max 8 liters/min
Pressure	-20 mbar to -300 mbar (in steps of 10 mbar)	-20 mbar to -300 mbar (in steps of 10 mbar)
Containers	Disposable secretion container system, 1000 ml	Disposable secretion container, 250 ml
Nominal mains voltage (mains-powered)	100 – 240V AC primary / 12V DC secondary	100 – 240V AC primary / 12V DC secondary
Maximum current	1.25 A	1.25 A
Mains frequency (mains-powered)	50 / 60 Hz	50 / 60 Hz
Rating	15 W (charging and operation) / 10 W (charging only)	15 W (charging and operation) / 10 W (charging only)
Current drawn	1.25 A at 12 V	1.25 A at 12 V
Rechargeable battery	7.4 V, 4.4 Ah – lithium ion	7.4 V, 4.4 Ah – lithium ion
Dimensions (H x W x D) in mm	290 x 259 + 100 (container) x 130 mm	165 x 220 x 90 mm
Weight (basic device)	Approx. 2.2 kg	Approx. 1.2 kg
Running time		
Mains	continuous operation	continuous operation
Battery	approx. 18 hours when the vacuum pump is at full capacity	approx. 18 hours when the vacuum pump is at full capacity
Operating mode	Intermittent Aspiration	Intermittent Aspiration
Degree of protection acc. IEC 60601-1	Type BF	Type BF
Protection class acc. IEC 60601-1	II	II
Noise emission	35 dB (A)	35 dB (A)
Ref #	100679	100678

For complete information on technical details, refer to the operating manuals for the *cuff* M and *cuff* S.

FloSure™

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