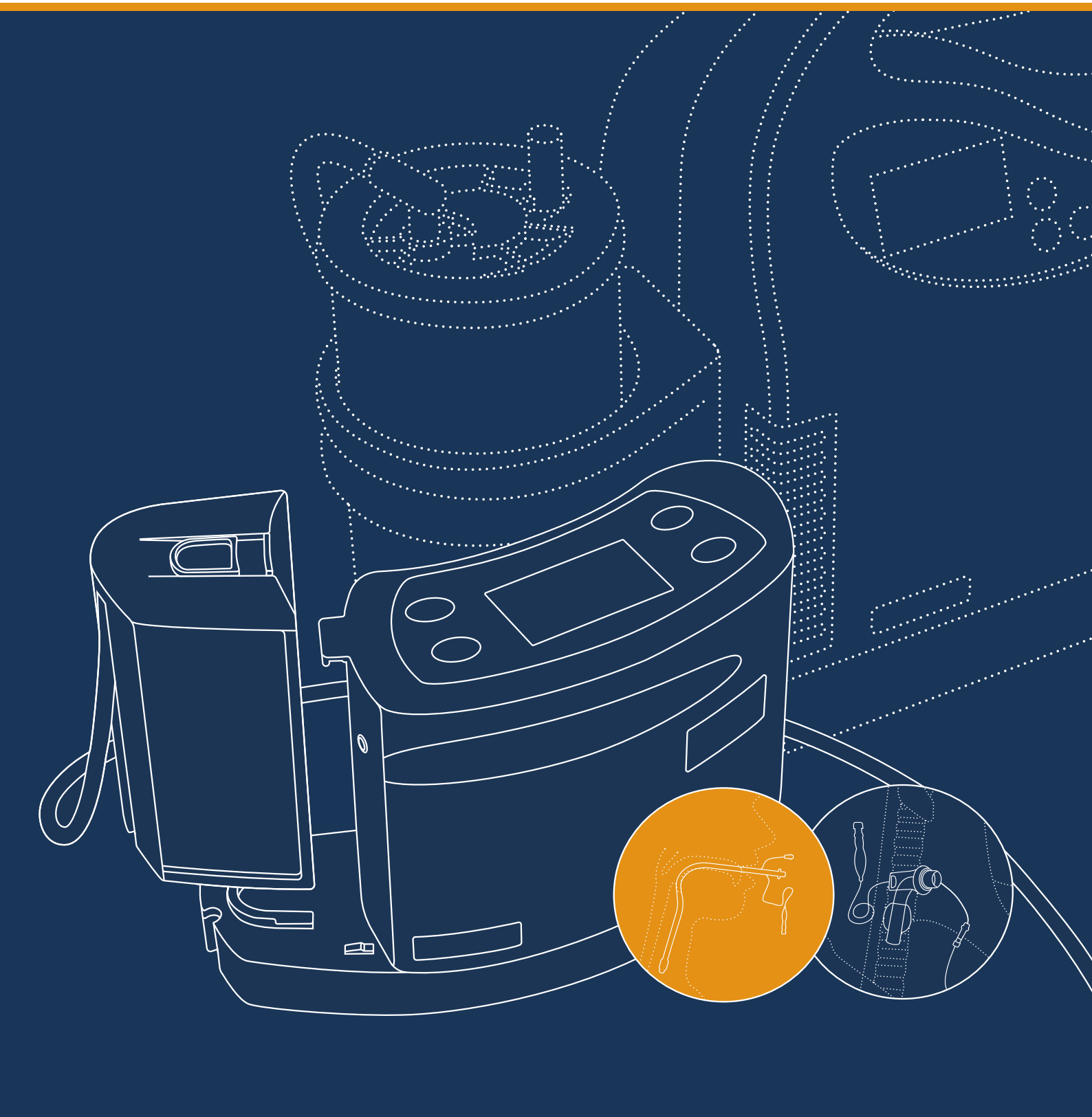
simex
Medizintechnik GmbH

A new direction for subglottic secretion management

automated subglottic aspiration system
simex *cuff* M & *cuff* S



philosophy & history

1994
Company Philosophy

simex Medizintechnik GmbH, a family owned company, was founded in 1994 and developed since to a knowledge-able and reliable partner for the medical professionals and distributors worldwide. Highest quality standards and excellent customer service has earned us recognition in the International Market. To maintain our quality standards we introduced our Quality Management System according to DIN EN ISO 13485 successfully in 1997.

At simex we are committed to develop, manufacture and supply innovative products of highest quality standards and focus on patient and customer satisfaction.

Our experienced team strives constantly to improve the internal processes and offer service to ensure that quality and safe products reach to patients and medical professionals.

We work closely with our qualified and experienced distribution partners to ensure consistent quality products and services.

10.000+
Products

With a range of over 10.000 quality surgical products simex is able to provide full support in procurement tenders and Turn-Key projects.

The product portfolio comprised of:

- Negative Pressure Wound Therapy System
- Automated subglottic aspiration System
- Portable suction devices
- General Surgical Instruments
- Micro- and Neuro Surgical Instruments
- Endoscopy Instruments

location

Our company is located since more than 20 years in Deißlingen, at the origin of the river Neckar between the towns of Villingen-Schwenningen and Rottweil.

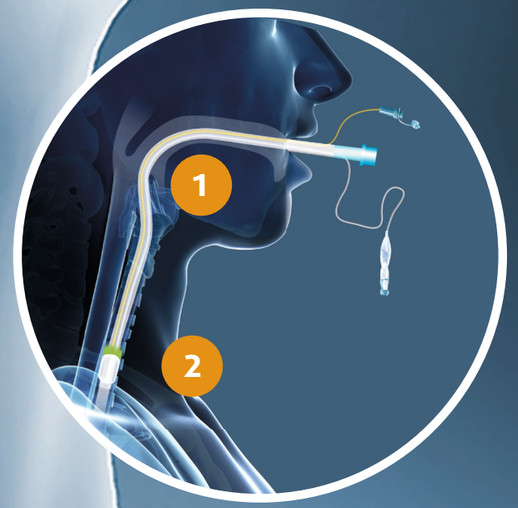


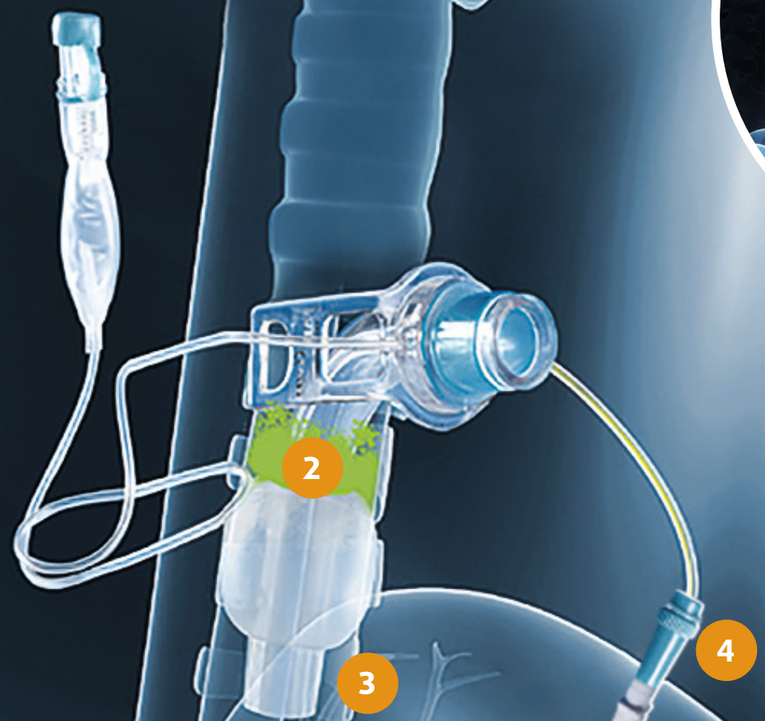
simex
automated subglottic aspiration system
innovation

Description

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

1. Endotracheal tube with special suction lumen
2. Subglottic secretion
3. Tracheal tube with special suction lumen
4. Subglottic secretion is removed via the simex *cuff* S or *cuff* M pump with the convenience of highly customized intermittent settings





simex *cuff* M
mobility miracle



Description

The simex *cuff* M is designed for subglottic extraction in order to help prevent ventilator-associated pneumonia (VAP)

Features

- lightweight
- low noise and little vibration (35 dB(A))
- simple operation, very safe and easy to use
- disposable secretion container with integrated gelling agent
- choice of battery or mains power
- integrated bacterial filter with overflow protection and odour prevention

Technical Data

Air-flow rate of aggregate	max. 8 l/min	**Operating mode**	Intermittent Aspiration
Pressure	-60 mbar to -300 mbar (in steps of 10 mbar)	**Running time**	
Containers	Disposable secretion container system, 250 ml	• Mains	continuous operation
Nominal mains voltage (mains-powered)	100 – 240V AC primary / 12V DC secondary	• Battery	approx. 18 hours when the vacuum pump is at full capacity
Maximum current	1.25 A	**Noise emission**	35 dB (A)
Mains frequency (mains-powered)	50 / 60 Hz	**Degree of protection acc. IEC 60601-1**	Type BF
Rating	15 W (charging and operation) 10 W (charging only)	**Protection class acc. IEC 60601-1**	II
Current drawn	1.25 A at 12 V	**Ref #**	100678-3
Rechargeable battery	7.4 V, 4.4 Ah – lithium ion	**CE identification**	CE0843
Dimensions (H x W x D)	165 x 220 x 90 mm		
Weight (basic device)	Approx. 1.2 kg		

Advantages for Patient

- Safe application, limited to -300mbar pressure
- Virtually silent operation
- Adjustable to patient secretion viscosity and volume
- Dry stoma
- Prevents skin inflammation
- Reduces bad smell
- Sooner weaning
- Reduced mortality

Advantages to Nursing Staff

- Saves nursing time due to automated intermittent subglottic aspiration
- Subglottic suction reduces lung infection (VAP)
- Closed aspiration system reduces risk of cross contamination
- Easy function control
- Alarm functions
- Fits to all standard ETT and ET tubes

Advantages to Clinical Outcome

- Reduces lung infection (VAP)
- Reduces endotracheal/bronchial suctioning
- Reduces mortality

Advantages to Hospital/Clinics

- Saves cost by preventing lung infection (VAP)
- Reduced cost for endotracheal suctioning
- helps to prevent 10 to 14 extended ICU days caused by lung infection

simex *cuff S*
large volume



Description

The simex *cuff* S is designed for subglottic extraction in order to help prevent ventilator-associated pneumonia (VAP)

Features

- low noise and little vibration (35 dB(A))
- simple operation, very safe and easy to use
- choice of battery or mains power
- double filter system protects the inside of the device against contamination
- to be used with a disposable secretion liners system and has various accessories

Technical Data

Air-flow rate of aggregate	max. 8 l/min	**Operating mode**	Intermittent Aspiration
Pressure	-60 mbar to -300 mbar (in steps of 10 mbar)	**Running time**	
Containers	Disposable secretion container system, 1000 ml	• Mains	continuous operation
Nominal mains voltage (mains-powered)	100 – 240V AC primary / 12V DC secondary	• Battery	approx. 18 hours when the vacuum pump is at full capacity
Maximum current	1.25 A	**Noise emission**	35 dB (A)
Mains frequency (mains-powered)	50 / 60 Hz	**Degree of protection acc. IEC 60601-1**	Type BF
Rating	15 W (charging and operation) 10 W (charging only)	**Protection class acc. IEC 60601-1**	II
Current drawn	1.25 A at 12 V	**Ref #**	100679-3
Rechargeable battery	7.4 V, 4.4 Ah – lithium ion	**CE identification**	CE0843
Dimensions (H x W x D)	290 x 259 + 100 (container) x 130 mm		
Weight (basic device)	Approx. 2.2 kg		

Advantages for Patient

- Safe application, limited to -300mbar pressure
- Virtually silent operation
- Adjustable to patient secretion viscosity and volume
- Dry stoma
- Prevents skin inflammation
- Reduces bad smell
- Sooner weaning
- Reduced mortality

Advantages to Nursing Staff

- Saves nursing time due to automated intermittent subglottic aspiration
- Subglottic suction reduces lung infection (VAP)
- Closed aspiration system reduces risk of cross contamination
- Easy function control
- Alarm functions
- Fits to all standard ETT and ET tubes

Advantages to Clinical Outcome

- Reduces lung infection (VAP)
- Reduces endotracheal/bronchial suctioning
- Reduces mortality

Advantages to Hospital/Clinics

- Saves cost by preventing lung infection (VAP)
- Reduced cost for endotracheal suctioning
- helps to prevent 10 to 14 extended ICU days caused by lung infection

subglottic aspiration system models
simex *cuff* S and *cuff* M

Description

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* S** and ***cuff* M** are special suction pumps designed and indicated for intermittent aspiration of subglottic secretions.

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.

Features

- Disposable secretion container with integrated bacterial filter and gelling agent
- Simple and uncomplicated menu control (color coded display)
- Virtually silent operation (35dBA)
- Simple, safe and easy to use
- 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 -60 to -300 mbar (10 mbar increments)
- Customizable ON/OFF times for Intermittent aspiration. „ON" time can be set from 10-60 seconds and „OFF" time can be set from 3-60 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* S and *cuff* M
- Safety alarm features for full canister and for low or fully discharged battery

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 crosscontamination and minimize incidence of infection

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

- The *cuff* S and *cuff* M are special subglottic aspiration systems designed and indicated for intermittent aspiration of subglottic secretions.
- The *cuff* S and *cuff* M are special 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 of intermittent subglottic aspiration with the *cuff* M and *cuff* S.[20]

VAP Facts

- 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 (multipurpose) 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]

„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."

Dr. med. Markus Wolf. Senior Physician Weaning Station, Department of Pneumology and Intensive Care. Asklepios Klinik Barmbek, Hamburg, Germany

„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* S/M" Stoma Therapist, Certified RN, Gesundheits Manager GmbH, Nuremburg, Germany

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