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.
Subglottic secretion is removed via the SIMEX cuff M or cuff S pump with the convenience of highly customized intermittent settings.
**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), 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.\(^6\)\(^-\)\(^7\) 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 (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.\(^6\)-\(^7\),\(^10\),\(^12\),\(^16\)-\(^19\)

References

20. Data on file

“In our facility in Nuremberg 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.”

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

Helmut Fendler
“Innovator of original concept for cuff MIS”
Stoma Therapist, Certified RN,
GesundheitsManager GmbH, Nuremberg, Germany
## Technical Detail

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