Simex[™] Automated Intermittent Subglottic Aspiration System product trial from July 5 to August 29, 2018

Introduction

Customer was contacted in June 2018 in order to assess their interest level in the Simex system, the only FDA cleared Subglottic Aspiration Device on the market. The product was to be utilized for ventilated patients. On July 5, 2018 sales representatives Hillery Royer and Mark Elenbaas were to show the benefits of the machine and how Simex can provide improved outcomes customer patients. The trial started with 4 Simex machines being placed on 4 separate patients. Customer approved algorithm based upon certain unique safety features of the Simex System with respect to pressure and time.

Patient #1(Room 110A to 109A) – July 5, 2018 @ 8:40 am – Continued on the device thru August 29, 2018

Comments; patient was on wall suction prior. Non-Viscous.

Settings: 15 seconds on, every 8 min, at 200 mbar (150 mmHg)

Outcome: Secretions have gone down and stoma healed within days of being put on the Simex Aspirated Approx. 200 - 250 ml per day. Completed 2 canisters + 200 ml on third canister.

Trach care started at 5-6 times per 12 hour shift and was reduced to the normal 1 per 12 hour shift. Stoma completely dry



Images of collection canisters filled with sputum

aspirated from Patient's subglottic area

Patient #2 (Room ICU 5) - 7/5/18 @ 8:30 am Discharged 7/28/18

Comments: Patient had viscous sputum with CRE. Patient was transferred to acute care hospital because of a different type of infection.



Images of Simex Aspiration System and collection canisters filled with sputum aspirated from Patient's subglottic

Patient #3 (Room 624 to 608) - 07/05/18 @ 2:20 pm Discharged

Comments: Patient was very unstable and mostly unconscious before being placed on Simex. Patient is now currently off the ventilator and phonating. Complete change in health status. Pt was weaned and decannulated, then transferred to Sub Acute Unit. This patient went home from SAU.

• <u>Settings:</u> 15 seconds on, every 15 min, at 200 mbar (150 mmHg)



7/13/18 - 700 ml

Patient #4 (Room 110B) - 07/5/18 @ 9:00am – Continued on the device thru Aug 29, 2018

Comments: Patient loves the Simex and told the nurses she will tackle them if they try to take away the Simex. Patient started crying happy tears and would like to be used in our printed material. She was able to articulate how much better she felt on Simex. Patient is only on Simex at night, her average aspiration is 366 ml per night hours. Speech has significantly improved (tone & less garbled)

- <u>Settings:</u> 20 seconds on, every 5 min, at 200 mbar (150 mmHg) nurse had determined viscous fluid
 - August 8, 2018Aug 12, 2018@2:30 3^{rd} canister = 2,400 ml
- **Outcome:** 1100 ml of fluid aspirated between July 5- 8, 2018

Conclusion:

Based upon the data collected, and most importantly on comments by customer, we have concluded that the Simex Subglottic device captures substantially more secretions when compared to standard suctioning techniques. Increased volume of secretions can promote decreased time on the ventilator and expedited weaning. Possible mitigation of lung infection.

In addition, Simex fully automated intermittent suctioning, when compared to standard manual suctioning, provided better patient comfort and a less traumatic procedural experience.

Finally, less handling of infectious materials by the nursing staff, and less interaction with those materials, is beneficial to both staff and patients.

Reference Articles of interest:

Using an Automated Intermittent Subglottic Aspiration System in Long-Term Care Facilities » Fendler H. RN, Director of Gesundheits Manager, Fain K., SLP

<u>http://flosuretechnologies.com/wp-</u> content/uploads/2016/07/Poster_Automated_Intermittent_Subglottic_Aspiration_System_In_LongTermCare_F NL092015-protected.pdf

VAP Prevention Strategies in Long-term Mechanically Ventilated Patients: Clinical Experience and New Approaches Involving Sublottic Tracheostomy Tubes and Automated Removal of Subglottic Secretions »

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 $\underline{http://flosuretechnologies.com/wp-content/uploads/2016/07/VAPPreventionStrategies in Longterm MVP at ients Spring 2016-webprotected.pdf$

<u>Return on Investment:</u>

The return on investment for use of Simex Automated Subglottic Aspiration System are:

- 1. 1.77 days ventilator days saved in ICU alone. The Simex can save the minimal national average of \$4,800 per day based upon the CDC documentation. https://www.cdc.gov/hai/vap/vap.html.
- 2. Cost savings associated with prevention of occurrence of aspiration pneumonia
- 3. There was a reduction of 5-6 stoma care per 12 hour shift, to the normal 1 stoma care per 12 hour shift. Showing a reduction of supplies and nursing time.
- 4. Dramatic reduction of wound care around the stoma. Reductions of antibiotic usage / antibiotic resistance epidemic.
- 5. Another benefit documented is patient transition to speaking valve, phonation and articulation cutting costs to keep them not dependent on vent time and costs.

While quality improvement initiatives have decreased HAI incidence and overall costs, much more remains to be done. As hospitals realize savings from prevention of these complications under payment reforms, they may be more likely to invest in such strategies

Approved Evaluation Algorithm



200 mbar or 150 mmHg 15 **SEC** Time ON

15 MIN Time OFF

Viscous Sputum

200 mbar (150 mmHg)

Extended ON Time to 20-30 SEC

OFF Time <u>15 MIN</u>

Non Viscous Excessive Fluid

Maceration weepy stoma included for long term 200 mbar (150 mmHg)

ON Time <u>15 **SEC**</u>

OFF Time 5 - 8 MIN

AARC Recommended Guidelines 200 mbar or 150 mmHg Adult Max 133 mbar or 100 mmHg Pediatric Max