Suction-Easy™ Technical Bulletin

E M Innovations
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Suctioning a patient is not a glamorous task, but in the presence of a blocked airway... **Nothing Else Matters**.

Undoubtedly, the ability to effectively clear the pharynx is one of the most critical of basic rescue skills. Suction-Easy is a simple, inexpensive solution to facilitate training and use for this aspect of airway management. It also provides you with the quickest, safest and most effective form of immediate oral suction. Suction-Easy is a **must have** in your first responder airway kit.

Suction-Easy has a unique double-valved design that allows continuous operation with one hand, while the other hand directs the suction tip throughout your patient's oropharynx. A consistent vacuum force is applied with each squeeze of the bulb and the material drawn into the bulb is expelled into an attached collection bag. You maintain excellent visibility throughout the procedure.

1. Instant Availability - There's no need to worry about batteries or electricity. Suction-Easy is available for immediate use. Just extend the suction tube and begin suctioning.

2. Powerful - Enough suction and caliper to rapidly and completely open the upper airway.

3. Reliable - With Suction-Easy, there's no down time and no clean up.

4. Fits All Hand Sizes - Ease of grip and compression regardless of hand size or grip strength.

5. Adequate Fluid Capacity - Total fluid capacity is in excess of 1,000 cc. enough to contain the entire excretion from the upper airway.

6. Safe - Contoured suction tip and controllable vacuum prevent tissue damage.

7. Easy, Safe Disposal - Just place in original package with exposed biohazard label. (The Suction-Easy system meets infection control requirements of containment, isolation and labeling.)

8. Small Design - 1/3 the size means minimal storage and carrying space requirements.

9. Lightweight - 1/3 the weight means minimal load added to bags.

10. Less Cost - 1/3 the cost of other oral suction devices currently available to personnel.

How Suction-Easy Works

Fail Proof

With Suction-Easy, a unique bulb design provides generation of consistent vacuum force, storage and protection of the large bore suction tube (9.5mm I.D.), a device easy to grasp and compress (regardless of hand size or grip strength), and most importantly, a device so compact, effective and affordable that no critical airway management event should fail due to *fluids in the oropharynx*. A double valved system promotes continuous operation with one hand, while the other hand directs the suction tip inside the patient's mouth. Material drawn into the bulb is expelled into a sealed collection bag. Total fluid capacity of the Suction-Easy system (bulb & bag), is in excess of 1,000cc. A 2-part label, on the resealable bag containing each new Suction-Easy, completes the system. The used Suction-Easy is placed back in its original package and secured with the pressure seal. The user peels off the top layer of the package label to reveal the international bio-hazard symbol. Infection control requirements of containment, isolation, and labeling are met in one simple step.

Patented Valve System

The Suction-Easy device is not a turkey baster; rapid shallow compressions of the pump provide quick large volume removal of oral contents even for the rescuers with small hands. There are two (2) flap valves in the system. The first is at the end of the large bore suction tube inside the bulb. The second is attached to the outlet port and is visible inside the collection bag. The Suction-Easy bulb is designed to provide a vacuum force of approximately 100mm Hg. generated by the "rebound" of the bulb after each squeeze. The force of the operator's grip does not affect suction pressure. (Gentler pressures can be achieved by shallow compressions of the vacuum bulb). Expulsion of contents from the bulb to the collection bag however, will directly reflect the force of each squeeze. The total capacity of Suction-Easy (vacuum bulb and collection bag) is well over 1,000cc's. This volume can be moved quickly with rapid shallow compressions of the pump.

Convenient Storage

A large portion of the suction tube is stored inside the vacuum bulb. The tube must be pulled out to its full length for proper operation of Suction-Easy. A positive stop/lock is felt when the tube is fully extended. The purpose of this feature is twofold. First, there is a very real risk of the suction tubing taking on a "cold set" if stored in one position for an extended period. We are well aware that if Suction-Easy becomes a standard component of first-in bags or kits, it will be jammed in along with many other essential items. Should the tubing become kinked, serious compromise to air and material flow may result, even to the extent of complete obstruction. Secondly, suction is of vital importance but used infrequently; for that reason the device must be as compact as possible so as not to take precious space from more routinely used items. Suction-Easy's size offers the possibility of carrying it on one's person, in turnout gear pockets, jumpsuits, and the like.

Suction-Easy™ Instructions For Use

The Suction Easy is a small, manual suction device for cleaning vomitus, mucus, blood and other foreign substances from the upper airway. It is easy to carry and store. Because it is manually operated, it requires little maintenance and is not dependent on batteries or other external power sources. It can be stored for extended periods of time and is instantly ready for use.

CAUTION: Suction Easy™ should be used only by persons who have received approved training in suctioning the oral airway. Improper use could result in injury to the patient. It is designed for use on adults and is not designed to be used on infants or children under the age of 8.

CONSTRUCTION: Suction Easy™ is made of a rigid plastic suction tube, a suction bulb and a collection bag for aspirated liquids. One-way valves prevent the backflow of aspirated contents.

INSTRUCTIONS FOR USE:

- Remove Suction Easy from the package. Pull the suction tube out until it stops.
- Clean any obvious foreign substances from the patient's airway by using finger sweeps.
- Grasp the suction bulb between your thumb and forefingers.
- Squeeze the suction bulb.
- Insert the suction tube into the back of the patient's throat. Do NOT insert farther than you can see.
- Release the suction bulb to remove the liquid from the patient's throat.
- Continue to squeeze and release the bulb to remove additional liquid.
- After the airway is cleared it may be necessary to take other steps to clear and maintain the airway.

CAUTION: Overfilling of the collection bag will result in fluid being released from the air vent.

Body Substance Isolation

Use of this device may result in your contact with contaminated body fluids. Use appropriate body substance isolation measures such as gloves.

Disposal

Suction-Easy is a single use device. It is designed for disposal after use. Do not attempt to clean and reuse this device. Dispose of it in a manner that assures body substance isolation of potentially infectious substances.

Storage - This device should be kept dry and stored between 10 ° F - 140° F.

Training Tips

For training, Suction-Easy may be used (and reused) with water, and still remain a valid device in the field.

The overflow, or collection, pouch is made of a very durable urethane plastic that should perform well under most emergency situations.

The vent is covered by a semi-permeable membrane which allows air, but not fluid to pass through. The integrity of this membrane will be maintained as long as fluids are not forced through under pressure; e.g., stepping on the bag, or continuing to squeeze the bulb once the reservoir bag is full. Once fluids have been forced through, leakage will continue until the membrane dries out. This property can be useful for training personnel in the use of the Suction-Easy. Students can evacuate clean water from a container or mannequin to get the feel of the device. Water can then be forced out through the vent to empty both the vacuum bulb and overflow pouch. Directing air into the suction tube will help dry the entire system. Once the air vent membrane dries completely it regains its semi-permeable qualities.

Biohazard Compliant Disposal

The Suction-Easy package has a two-part label. User instructions appear on the first layer. Once the device has been used this layer is peeled off to reveal a biohazard-warning label. The intention is to provide for the user a simple means of containing, isolating, and labeling the now contaminated device for easy disposal.

Suction-Easy is designed for single patient use only. Suction-Easy is not to be cleaned and reused once contaminated.

Testing

Review of compliance to BS EN ISO 10079-2
"Medical Suction Equipment
Part 2. Manually powered suction equipment"

Purpose

This report is a section by section review of the compliance of the Suction Easy product with ISO 10079-2 Medical suction equipment, Part 2. Manually powered suction equipment. Included are test results of the performance of the Suction Easy.

Sections 1 through 3

Sections 1 through 3 inclusive are Scope, Normative Reference, and Definitions. Performance and design criteria are not covered in these sections

Section 4

Section 4 covers performance of devices intended to be cleaned, disinfected, or sterilized. Suction Easy is a single use, disposable, non sterilizable device. This section therefore does not apply.

Section 5

Section 5.1 concerns connectors between different parts of the vacuum system Suction Easy does not have separate parts. Therefore section 5.1 does not apply.

Section 5.2.1 states that suction tubing must have an inside diameter of at least 6 mm. Suction Easy's tracheal tube has an inside diameter of 9.5 mm . It also states that the tubing must not collapse more than 50% when full vacuum is applied. Suction Easy does not have any measurable change in inner diameter when full vacuum is applied.

Section 5.2.2 concerns foot operated equipment and does not apply.

Section 6

Section 6.1 requires that the device be operated by one person unaided. Regarding Suction Easy, this is obvious by inspection.

Section 6.2 concerns dismantling and reassembly. Suction Easy is not intended to be dismantled and this section does not apply.

Section 6.3 requires a mechanical shock test drop from one meter) per A.2. Suction Easy passes this test.

Section 6.4 requires a drop into water then test of performance. Suction Easy passes this test.

Section 6.5 concerns stability of a device, that is that it will not tip over during use. Suction Easy will work in any orientation and this section does not apply.

Section 6.6 concerns overfill and prevention of liquids entering the suction line downstream of the overfill device. Suction Easy is intended to operate after overflow and this section does not apply.

Section 6.7 concerns vacuum indicators. Suction Easy does not have a vacuum indicator.

Section 7

Section 7.1 concerns maximum dimensions. Suction Easy meets the requirement for fitting through a rectangular opening having dimensions of 800 mm x 300 mm.

Section 7.2 concerns maximum weight. Suction Easy meets the requirement for weighing less than 6 kg.

Section 7.3.1 concerns the minimum inlet diameter of the collection container which must be at least 6mm. Suction Easy's meets this requirement as its inlet is 9.5 mm.

Section 7.3.2 concerns minimum volume of the collection container which must be at least 500 mL. Suction Easy's meets this requirement as its collection capability is 1 L .

Section 7.3.3 concerns devices not intended for field use and does not apply.

Section 7.3.4 concerns a vacuum test to check that the collection container will not implode and does not apply to the Suction Easy bag as it cannot implode.

Section 8

Section 8.1 concerns the vacuum level attainable, which is called out as -40 kPA. Suction Easy is specified to be capable of -14 kPA and is tested during manufacture to that level.

Section 8.2 requires that 200 mL of simulated vomitus be evacuated within 10 seconds. Suction Easy meets this requirement.

Section 8.3 concerns free air flow of a vacuum system. Suction Easy does not have a continuous vacuum capability and this requirement does not apply.

Section 9

Section 9.1 requires the device attain vacuum per 8.1 and flow per 8.2 after cold (-40˚C) and hot (60˚C) storage. Suction Easy meets this requirement.

Section 9.2 requires the device operate and attain vacuum per 8.1 and flow per 8.2 at hot (50˚C) and cold (-18˚C) temperatures. Suction Easy meets this requirement.

Section 10

Requires marking with the name of the manufacturer or supplier and model number. Suction Easy meets this requirement.

This also requires marking of the exhaust opening and inlet connection. Since Suction Easy does not connect to a vacuum system, these requirements do not apply.

Section 11

Requires specific language and information in the instructions. Suction Easy complies with this section.

Temperature Testing

Background

The Suction Easy product uses a resilient squeeze bulb to produce vacuum for suctioning an airway prior to CPR. A collection bag and filter provide capacity for at least a liter of suctioned fluids. The various components must allow a suction level of 100 mmHg minimum over the temperature range of 50°C to -18°C (122°F to -0.4°F). In addition, the device must continue to perform after being stored at temperatures from 60°C to -40°C (140°F to -40°F). This test procedure was intended to challenge the Suction Easy's construction and materials used to insure that the device will continue to perform adequately.

The low and high temperature tests are derived from ISO10079-2 Medical Suction Equipment - Part 2 Manually powered suction equipment standard.

Procedure

This testing was performed on five completed Suction Easy devices.

Room temperature test

The suction level of all five devices was tested at room temperature. A vacuum level of 100 mmHg minimum, when measured at the end of the tracheal tube, was held for 4 seconds on each. PASSED

Low temperature operation test

The Suction Easy devices were placed in an environmental chamber at -18°C ± 5°C (-0.4°F ± 9°F). After a four hour temperature soak time, the Suction Easy devices were removed and within 60 seconds of removal the vacuum level was tested. A vacuum level of 100 mmHg minimum was held for 4 seconds on each. PASSED

High temperature operation test

The same Suction Easy devices were placed in an environmental chamber at 50°C ± 5°C (122°F ± 9°F). After a four hour temperature soak time, the Suction Easy devices were removed and within 60 seconds of removal the vacuum level was tested. A vacuum level of 100 mmHg minimum was held for 4 seconds on each. PASSED

Low temperature storage test

The same Suction Easy devices were placed in an environmental chamber at -40°C ± 5°C (-40°F ± 9°F). After a minimum of 24 hours, the Suction Easy devices were removed. The Suction Easy devices were allowed to come to room temperature for a minimum of four hours then the suction ability of the devices was tested. A vacuum level of 100 mmHg minimum was held for 4 seconds on each. PASSED

High temperature storage test.

The same Suction Easy devices were placed in an environmental chamber at 60°C ± 5°C (140°F ± 9°F). After a minimum of 24 hours, the Suction Easy devices were removed. The Suction Easy devices were allowed to come to room temperature for a minimum of four hours then the suction ability of the devices was tested. A vacuum level of 100 mmHg minimum was held for 4 seconds on each. PASSED

Acceptance Criteria

All five Suction Easy devices tested passed the vacuum level test after all of the above testing.

Specifications

Vacuum	100mmHg
Collection Volume (bulb and bag)	1,000 cc
Weight:	190 g (6.2 oz.)
Overall Package Dimensions (can be folded into 9″ x 4″):	10-5/8" x 11-7/8"

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