

~~K 593274/A~~

**TEAM International**  
Division of MAET Industries Inc.

4215 Renoak Court, Mississauga  
ON, Canada, L5C 4K3

Tel: (905) 848-0876  
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*Dr. Carroll*

January 27, 2000

Ms. Carroll O'Neill  
FDA - HFZ 450  
9200 Corporate Blvd.  
Rockville, MD, 20850

4167 00 MAR 13 1999

**Re: K993284 - Request for Evaluation of Automatic Class III Designation**  
Trade Name: QuickAir Choke Reliever, Model 59-001A

**Dear Carroll,**

Thank you for Celia M. Witten's letter dated December 29, 1999. On behalf of MedMira Laboratories Inc., we are requesting that the FDA consider reclassification of the above device to Class II from automatic Class III.

The device is designed as an adjunct (or procedural aid) to the existing method for first aid for choking as approved by the American Heart Association. The device does not represent a new or unknown method of relieving foreign body airway obstruction as it simulates the Heimlich maneuver.

Please refer to our 510k submission dated September 29, 1999 for the following:

- Description of the device
- Safety Testing: Detailed information on device safety testing (in vitro), by Mosaic Technologies Inc. This in vitro testing showed that maximum pressures on the abdomen with the device (using 16 volunteers instructed to use all their strength) compared to pressure on the abdomen using the conventional abdominal thrust were similar. The volunteer rescuers were instructed to exert the most force possible so as to obtain meaningful safety measurements.

This submission includes the following three sections of information: technical description of the manikin, discussion of previous effectiveness testing, and 'human factors testing report'.

Thank you for considering our request for reclassification of device. I will be in the Washington area twice in February, and would like to stop in to see you briefly to answer any questions you may have.

Thank you,

*Wayne Witbeck*  
Wayne Witbeck

00P-1117

CCP 1  
28 JAN 00 11 3  
FDA/CDRH/ODE

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February 22, 2000

Ms. Carroll O'Neill  
FDA – HFZ 450  
9200 Corporate Blvd.  
Rockville, MD, 20850

**Re: K993284 – Additional Information to be included in our Request for  
Evaluation of Automatic Class III Designation**

Trade Name: QuickAir Choke Reliever, Model 59-001A

**Dear Carroll,**

This letter addresses some additional issues related to our 510k and device reclassification request.

**1. 'Errant' Page**

Inadvertently, we submitted a page with a lady simulating a choking situation, using our product. This page should not have been submitted to the FDA as we had previously removed it from our labeling and we do not intend to make such statements.

**2. Spirometer Pressure Calibration Methods**

(Note: the same spirometer was used for all test results provided to the FDA except for the labeling test, where absolute pressure accuracy was not considered to be as critical)

We are pleased to explain the calibration methods used in the testing programs as follows.

- Spirometer: Model CPF/S/RPM System with RPM software
- Manufacturer: Med Graphics Inc., Minneapolis, MN
- Computer: 386SX
- Pressure calibration standard instrument: Dwyer water 'u' tube manometer
- Installation, training and technical support: provided under contract by ARS Vital Aire

Calibration was an absolute requirement of the spirometer software each time the computer was turned on. Pressure was applied to the spirometer's mouthpiece by a syringe and the water manometer at the same time through a 'T' connection in the pressure tube. Calibration covered the full range of '0' to '100' cm. of H<sub>2</sub>O in increments of 20 cm. as recommended by the manufacturer. Pressure calibration variations were always less than 1%.

### 3. Technical Description of the Manikin

The question is .... How do we know that the manikin used in the 510k submission (by Mosaic Technologies Inc.), and also used in the human factors testing (by Robert Brennan) accurately represents the human body?

*Answer:*

There are two reasons why Precious Life Saving Products Inc. believes the manikin is an accurate representation of the human body (apart from the fact that it is anatomically accurate).

- a. Simulaid Inc., Woodstock, NY, the company which designed the manikin worked over a period of time with several Emergency Management Services people, including paramedics and emergency cardiac care technicians to refine the manikin's "abdominal pressure" vs. "pressure-at-mouth" ratio so that it represented a typical adult "choke-rescue" response. There is no known technical information in the literature which gives design information to enable construction of a manikin having typical abdominal vs. mouth pressure response. To do this research now, would be considered 'dangerous'.
- b. The safety testing by Mosaic technologies in September 1999, and submitted as part of our 510k, included measurements of both abdominal surface pressure and resulting air pressure at the mouth (as recorded by the same RPM spirometer as used in our own previous testing). In the 510k tests by Mosaic Technologies Inc., sixteen (16) human volunteers were instructed to use a strong force using the device or the conventional Heimlich.

The resulting pressure at the mouth pressure stated in the 510k (Mosaic Technologies' Study, pg. 50, para. 3) is:

- Conventional Heimlich (upright) = 20 +/- 15 cmH<sub>2</sub>O or 15 +/- 11.5 mmHg

The above pressures at the mouth using sixteen volunteer rescuers (in the Mosaic Technologies Inc. studies) compare closely to pressure at the mouth measurements in other scientific studies on humans, as summarized in the following table:

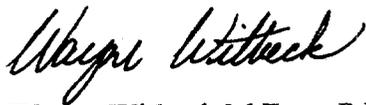
Note that if we take all the data from other published scientific studies; i.e., 11, 7, 13, 31, 25, 15, 12 and 31 mmHg., the average and standard deviation is 18 +/- 9.5 mmHg. This compares closely with the 15 +/- 11.5 mmHg found when using the manikin.

Abdominal pressures were not measured in the other scientific studies, and therefore cannot be compared with our 510k abdominal pressure data.

**Previous Scientific Studies Investigating The Heimlich Maneuver**

Investigator	Maximal Pressure Measured at the Mouth		Comments
	Resting Lung Position (mm Hg)	End of Inspiration (mm Hg)	
<b>Natural Cough</b> Gordon et al.	72	115	Conscious volunteers
<b>Abdominal Thrust</b> Gordon et al.	11	15	6 anaesthetized, age 21-56
Ruben et al.	7	12	12 anaesthetized, aged 32-77
Ruben et al.	13	31	6 cadavers, full force used
Heimlich et al.	31	-	10 conscious volunteers
Day et al	25	-	

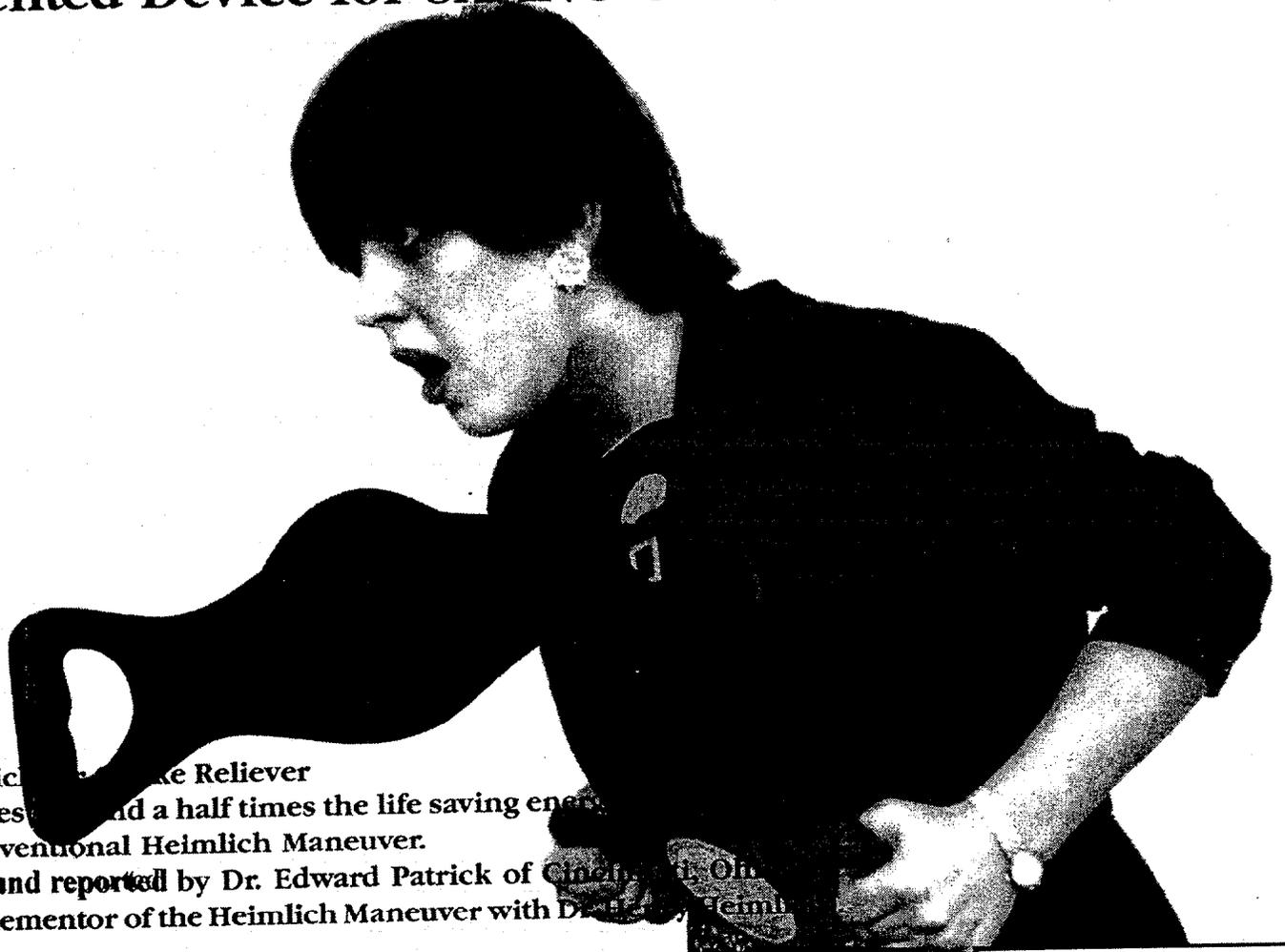
Prepared by:



Wayne Witbeck M.Eng., P.Eng.

# Quick Air Choke Reliever

Patented Device for **SAVING CHOKING VICTIMS**



The Quick Air Choke Reliever generates **twice and a half times** the life saving energy of the conventional Heimlich Maneuver.  
**(Tested and reported by Dr. Edward Patrick of Cincinnati, Ohio, co-implermentor of the Heimlich Maneuver with Dr. Henry Heimlich)**

**Extends the reach of a smaller person**



**Self-administer if choking alone**



**Easy to learn  
Easy to apply**

**Easier to use by the physically weak**

**Comes with training poster and booklet**

**Show device and booklet to friends**

**The QuickAir Choke Reliever is Emergency Equipment**

**Store in prominent place where food is consumed**

**Once a year, review poster and booklet**

## **1. Technical Description of Manikin**

The manikin used in the in vitro safety testing reported in the 510k submission has the following technical characteristics making it suitable for estimating the potential for abdominal injuries.

- Manufactured by Simulaids Inc., model name "choker" Tel: 914-679-8996 Reference Mr. Greg Zindulka, Research and Development Manager.
- Designed to expel obstruction when abdominal thrust is properly performed
- Anatomically accurate rib cage, xiphoid process, umbilicus and jugular notch are clearly identified
- The manikin is designed to be life-like and accurate with respect to abdominal pressures vs. pressure at the mouth. Manikin development was done over a period of years using the expertise of many emergency cardiac care professionals who reported to Simulaids Inc. on design changes from on-going use in the field.
- The technical compression information can be found on the attached technical bulletin from IPI Corporation which makes the foam interior of the manikin. This foam gives the manikin's abdomen an anatomically accurate abdominal compressibility.

## choking manikins

---

Completely realistic manikins available in child, adolescent, and adult sizes. Each life-size head and upper torso manikin allows practice of abdominal thrust, chest thrust, and back blow procedures for cleaning a blocked airway. Manikins are made with specially selected durable vinyl to create tactile realism. When correct clearing procedures are performed, the manikin will expel the object causing the obstruction. Large beans and simulated hot dog (provided) make excellent, practice obstructions. The obstruction object is placed in the manikin's oral cavity after performing mouth sweep. When back blows, or abdominal or chest thrusts are administered, the increased air pressure in the chest will impel the object from the mouth. Each manikin has a ribcage, xiphoid process, and jugular notch to provide anatomical reference points. Manikins include beans, shirt, and tough nylon stadium bag filled with web straps. Clothing and bag are fabric U.S.A.

### **Adult Choking Manikin with Carry Bag**

Size: 11" x 18" x 10". Sh. Wt. 16 lbs.

No. 1602 - \$225.00

# SIMULAIDS, INC.

PO Box 807/12 Dixon Ave. Woodstock, NY 12498  
(914) 679-2475

Toll Free: 800-431-4310

<http://www.simulaids.com>

FAX (914) 679-8996

January 26, 2000

MEDMIRA

Attn: Wayne Witback

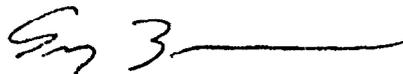
Wayne,

Here's a bulletin sheet on the foam used in our choking manikin. If you require additional information please contact I.P.I. I'm sure they would be happy to help.

As the time comes to release your device, SIMULAIDS would be interested in discussing a possible alliance. Perhaps selling our manikin with your device.

If Medmira is interested, contact Jack McNeff, our Sales Manager, who will work out discount and other details.

Regards,



Greg Zindulka  
Research & Development Manager

GZ/bam

*oguy*  
P. 101

**ISOFOAM® Technical Bulletin**



**IPI** A Division of PMC, Inc.  
505 BLUE BALL ROAD  
P.O. BOX 70  
ELKTON, MD 21922-0070

PHONE: (410) 392-4800  
FAX: (410) 398-7391

**ISOFOAM® F-1318  
POLYURETHANE FLEXIBLE FOAM SYSTEM**

**Description**

**ISOFOAM® F-1318**  
polyurethane chemical foam system is a two component system designed to produce a low density, flexible foam for specialty applications. This molded article can be made with this system which provides good processing characteristics, excellent flowability, fast cure times and may be molded with or without vinyl backing.

**ISOFOAM® F-1318**  
isocyanate component is a polymer MDI (polymer diisocyanate) containing reactive isocyanate groups.

**ISOFOAM® F-1318**  
Resin component is a combination of polyols, catalyst, surfactants, and blowing agents.

**Typical Hand Mix Reactivity**

1/2 Time, Secs.	10
1/4 Time, Secs.	20
1/2 Time, Min:Secs.	2:20
1/4 Time, min	3:2

**Typical Handling Characteristics**

	F-1318A	F-1318W
Viscosity, cps @ 25°C	350	1900
Specific Gravity @ 25°C	1.19	1.03
Mixing Ratio	100	180

**Typical Physical Properties**

Molded Density, pcf	3.6
Tensile, psi	10
Elongation, %	70
Tear, pli	.7
Compression Set, %	4
ILD 25%	50
65%	140
25% R	43

**THESE ARE TYPICAL PROPERTIES AND ARE NOT MEANT TO BE INTERPRETED AS SPECIFICATIONS.**

10/19/04  
10/19/04

## 2. Discussion of Device Effectiveness

### *QACR Test Results*

Precious Life Saving Products Inc.'s tests conducted in 1994 on 10 "victim-rescuer" combinations measured the air pressure generated at the mouth of the "victim" by the "rescuer" applying (at different times) the Heimlich maneuver, and the QACR device.

A Med-Graphics RPN spirometer connected to a 486 PC computer produced "pressure vs. time" graphs for each of the 10 "victim-rescuer" combinations (see appendix 'A'). The peak pressure and the duration of the pressure pulse at the base of the pressure-time curve were read directly from the paper printout of the computer-generated graph. These pressure peaks (indicated numerically on the computer screen in cmH<sub>2</sub>O) and time duration data were tabulated as shown in Table A-1, and summarized in Table 2. Note that the Heimlich Maneuver, using the human fist produced an average peak pressure of 14.4 mm Hg at the mouth (of the 10 victims). This compares with peak pressures found by most of the researchers listed in Table 1 below. Dr. Heimlich's and Dr. Patrick's studies found that effectiveness of any choke relieving method varies as the pressure measured at the mouth, integrated over the time period of the pressure pulse.

**Table 1: Choke Relieving Methods - Scientific Study Results**

Investigator	Maximal Pressure Measured at the Mouth		Comments
	Resting Lung Position (mm Hg)	End of Inspiration (mm Hg)	
<b>Natural Cough</b> Gordon et al.	72	115	conscious volunteers
<b>Abdominal Thrust</b> Gordon et al.	11	15	6 anaesthetized, age 21-56
Ruben et al.	7	12	12 anaesthetized, aged 32-77
Ruben et al.	13	31	6 cadavers, full force used
Heimlich et al.	31	-	10 conscious volunteers
Day et al	25	-	
<b>Back Blows</b> Gordon et al.	25	45	6 anaesthetized, age 21-56
Ruben et al.	18	24	6 cadavers, full force used
Day et al.	13	-	conscious volunteers
<b>Chest thrust</b> Gordon et al.	18	19	6 anaesthetized, age 21-56
Ruben et al.	15	22	12 anaesthetized, aged 32-77

1. Heimlich HJ, Patrick EA: The Heimlich Maneuver; best technique for saving any choking victim's life. Postgraduate Med 1990;87: 39-53.

### *Longer Pressure Pulse*

The QACR handles flex toward the victim as he/she pulls back on the handles. During this flexing process, potential energy is stored in the handles as well as the victim's abdomen. With the standard Heimlich Maneuver, potential energy is stored only in the victim's abdomen, but not in the rescuer's arms (since they are not flexible). As the rescuer releases the handles, they straighten out, maintaining pressure on the victim's abdomen for a longer period of time than when using the fist. This longer compression time is due to the fact that as the rescuer releases pressure on the handles, the stored potential energy in QACR's handles is released, maintaining pressure of the impeller ball on the victim's abdomen as the rescuer releases his/her compression thrust. This additional time of pressure exertion is particularly important when a smaller or weaker rescuer is attempting to save the life of a large or obese person.

**Table 2: QACR Testing - Precious Life Saving Product Inc.**  
(see Table A-1 for details)

HM vs. QACR	Heimlich Maneuver	QACR	Comments
Average peak pressure (mm Hg)	14.4	32	7 conscious volunteers -standing
Average duration (seconds)	0.81	1.04	7 conscious volunteers -standing

### Independent Third Party Testing

Dr. Patrick of Cincinnati, Ohio, used the principles of physics to show that the Heimlich maneuver was more effective than the backslap. PLSP Inc. commissioned Dr. Patrick to conduct independent third party trials of PLSP's device. Dr. Patrick's report is found in Appendix 'B'. The results are summarized in the following table.

**Table 3: QACR Testing by The Patrick Institute**

HM vs. QACR comparison	HM with Fist* (area under pressure-time curve)	QACR (area under pressure-time curve)	Comments
Supine	1.0	1.5	6 conscious volunteers -
Standing	2.1	3.5	7 conscious volunteers - standing
Self (standing)	1.0	1.09	11 conscious volunteers - standing

Dr. Patrick showed that the area under the pressure pulse curve relates to potential and kinetic energy available to relieve a choking situation. Values are normalized with a value of 1.0 assigned to the lowest result, i.e., without the QACR on supine volunteers.

#### *Summary of Results*

PLSP's own performance trials (Appendix 'A'), as well as the independent third party evaluation by The Patrick Institute in Cincinnati, Ohio, (Appendix B) found that abdominal thrusts using the QACR produce at least 50% more area under the "pressure-time" pulse curve as compared to conventional abdominal thrusts using the fist. The reasons for this superior performance are likely:

- **Increased peak pressure at the mouth** with the device, over using the human fist, is likely results from the fact that with the conventional method, the rescuer's wrist impinges on the victim's lower rib, resulting in less abdominal pressure. The device does not impinge on the ribs.
- **Increased time of the pressure pulse** is observed with the device due to the flexible handles, which store potential energy, as opposed to the human wrist, and arm, which are relatively non-elastic, and cannot store potential energy during the abdominal thrust procedure.

**Appendix A**

**Test Results**

**by**

**Precious Life Saving Product Inc.**

Table A-1: PLSP Test Results, 1994

Test No.	Victim	Gender	Age	Wt. (lb.)	Height (inches)	Rescuer	Height (inches)	Weight
1	R. Marcucci	M	25	200	71	Self	71	200
2	W. Witbeck	M	48	190	72	S. Larose	62	252
3	S. Larose	F	46	252	62	W. Witbeck	72	190
4	S. Larose	F	46	252	62	W. Witbeck	72	190
5	T. Rudmik	M	40	195	73	Dr. Anderson	63	145
6	L. Rudmik	M	15	150	71	T. Rudmik	73	195
7	T. Rudmik	M	40	195	73	Dr. Anderson	63	145
8	W. Witbeck	M	48	190	72	Dr. Anderson	63	145
9	Dr. Anderson	M	63	145	69	W. Witbeck	72	190
10	K. Jeanes	F	26	120	69	Pollyanna	60	100

Pulse Pressure Levels (P) and Time Duration (T)

Test No.	Test Date ('94)	Heimlich			QACR		
		Pressure (mm Hg)	Duration (seconds)	Effectiveness P x T*	Pressure (mm Hg)	Duration (Seconds)	Effectiveness P x T*
1	30-Aug	11	0.5	5.5	18	0.5	8.9
2	01-Sep	24	1.0	23.6	46	1.0	45.7
3	01-Sep	27	1.0	26.9	46	1.5	69.2
4	02-Sep	24	1.1	26.8	59	1.4	82.6
5	09-Sep	14	1.0	14.0	22	1.5	33.2
6	09-Sep	10	0.5	5.0	19	0.5	9.5
7	09-Sep	12	0.5	6.0	30	0.5	15.1
8	11-Sep	27	0.8	20.0	45	1.0	45.0
9	11-Sep	10	1.2	11.5	16	2.0	32.4
10	20-Sep	10	0.5	5.0	19	0.5	8.6
<b>Averages</b>		17	0.8	14.4	32	1.0	35.0

\* Effectiveness values are directly related to the magnitude of the areas under the P-T graphs as calculated per Dr. Patrick's energy model, see Section 1.

**Table A-2: PLSP Test Results, August 1995**

Nos. 1 - 10 (September, 1994 @ Mississauga, Canada)

Nos. 11 - 27 (August, 1995 @ Toronto, Canada)

No.	Victim	Sex	Age	Weight (lb.)	Height (inches)	Rescuer	Result Any discomfort reported immediately after test, and one hour following
1	R. Marcucci	M	25	200	71	Self	No
2	W. Witbeck	M	48	190	72	S. Larose	No
3	S. Larose	F	46	252	62	W. Witbeck	No
4	T. Rudmik	M	46	252	62	W. Witbeck	No
5	W. Witbeck	M	40	195	73	Dr. Anderson	No
6	L. Rudmik	M	15	150	71	Dr. Anderson	No
7	T. Rudmik	M	40	195	73	W. Witbeck	No
8	W. Witbeck	M	48	190	72	Pollyanna	No
9	Dr. Anderson	M	63	145	69	K. Jeanes	No
10	K. Jeanes	F	26	120	69	K. Jeanes	No
11	G. Bess	M	19	198	71	K. Jeanes	Minor discomfort, OK after 5 minutes
12	Abdifutah	M	16	101	64	K. Jeanes	No
13	P. Dhillon	M	20	150	71	K. Jeanes	No
14	M. Pahnke	M	34	150	66	K. Jeanes	No
15	Z. Marjanovic	M	33	108	66	K. Jeanes	No
16	C. Wilson	M	19	140	71	K. Jeanes	Felt pressure but not hurting
17	B. Marjanovic	M	41	225	75	K. Jeanes	No
18	J. Martin	M	53	163	65	Dr. Christink	No
19	T. Bramer	M	39	150	67	Dr. Christink	No
20	G. Tait	M	34	200	72	Dr. Christink	Felt pressure but no pain
21	R. Bodner	M	21	190	71	Dr. Christink	No
22	G. Hallberg	F	51	130	69.5	Dr. Christink	No
23	C. Royer	F	54	135	69	D. Witbeck, RN	No
24	M. Gulloch	F	60	140	65	D. Witbeck, RN	No
25	C. Samuel	F	35	125	65	D. Witbeck, RN	No
26	G. Thompson	M	36	206	70	Dr. Christink	No
27	A. Castellana	M	25	170	71	Dr. Christink	No

**Test Method:**

Each volunteer was given the 'First Aid for Choking' booklet and/or shown the training video. Under supervision of either a doctor / registered nurse, each 'victim' was given the Heimlich maneuver with the QuickAir Choke Reliever. Each volunteer was asked to report any discomfort or injury; immediately following the test, after 5, 15 and 60 minutes later.

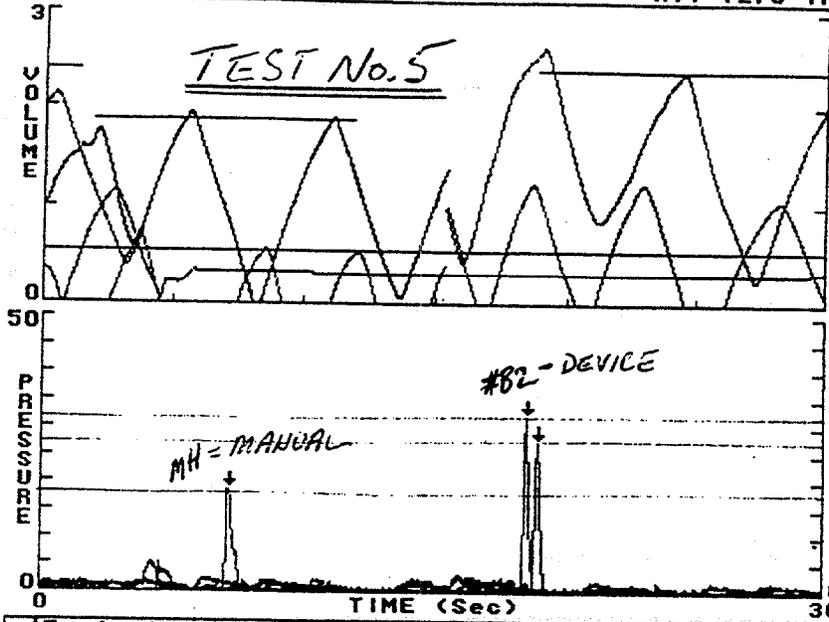
**Results:**

No volunteer reported any injury, however, three did experience minor discomfort, but without pain. After five minutes, all three reported that the discomfort was gone.





Name: Tom Rudmik ID: #B2 Date: 9/09/94  
 Sex: M Age: 40 yr Ht: 72.0 in Wt: 192.0 lbs BSA: 2.09 m<sup>2</sup>

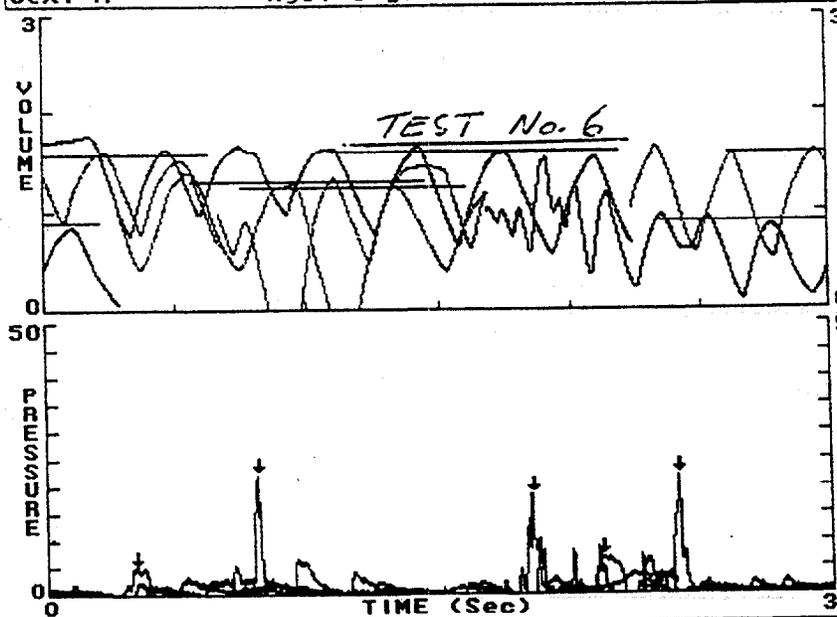


EXPIRATORY			
Test #	Volume	% TLC	cmH2O
1	1.50		6
2	0.70		13
3	0.70		13
4	0.36		14
5	0.48		28
6	0.15		32
7	1.66		19

Expiratory Muscle Forces

Start		Clear	Delete	Setup		Select		Tests	QUIT
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Name: Luke rudmik ID: #B2 Date: 9/09/94  
 Sex: M Age: 0 yr Ht: 0.0 in Wt: 0.0 lbs BSA: 0.00 m<sup>2</sup>



EXPIRATORY			
Test #	Volume	% TLC	cmH2O
1	0.92		22
2	0.90		23
3	0.05		7
* 4	0.01		5
5	0.14		19

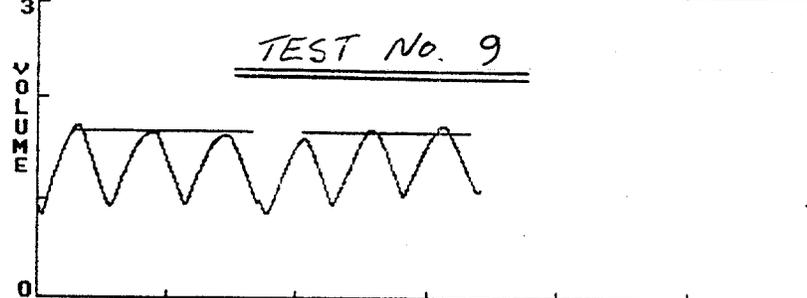
Expiratory Muscle Forces

Start		Clear	Delete	Setup		Select		Tests	QUIT
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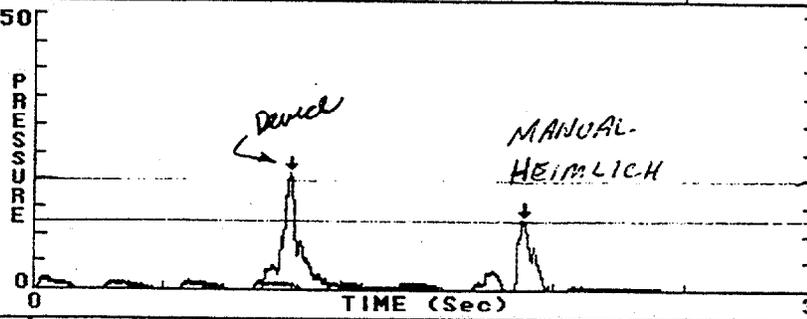
\* lowest of 3 manual breaths not considered.  
 Average of 7 cm H<sub>2</sub>O and 19 cm H<sub>2</sub>O used = 13 cm H<sub>2</sub>O or 10 mm Hg



Name: Dr. A. Anderson <sup>65</sup> ID: #B2 Date: 9/09/94  
 Sex: M Age: 60 yr Ht: 71.0 in Wt: 180.0 lbs BSA: 2.02 m<sup>2</sup>



EXPIRATORY			
Test #	Volume	% TLC	cmH2O
1	0.35		6
2	0.36		2
3	0.47		5
4	0.44		4
5	0.17		3
6	0.57		15
7	0.62		4
8	0.66		5
9	0.69	Device = 22	
10	0.58	Manual = 13	

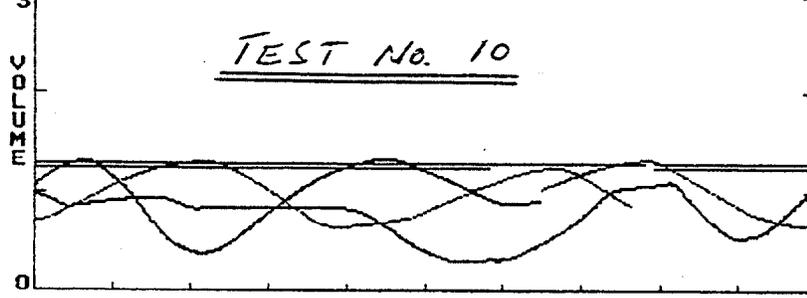


Expiratory Muscle Forces

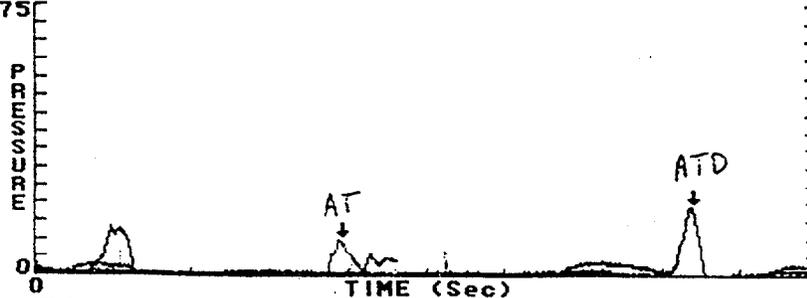
Start		Clear	Delete	Setup		Select		Tests	QUIT
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= 16.  
= 9.

Name: JK ID: #B2 Date: 9/20/94  
 Sex: F Age: 26 yr Ht: 65.0 in Wt: 145.0 lbs BSA: 1.73 m<sup>2</sup>



EXPIRATORY			
Test #	Volume	% TLC	cmH2O
1	0.42		8
2	0.32		19
3	0.41		10



Expiratory Muscle Forces

Start		Clear	Delete	Setup		Select		Tests	QUIT
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AT = manual abdominal thrust 10 cm H<sub>2</sub>O = 7.4 mm Hg  
 ATD = abdominal thrust with device 19 cm H<sub>2</sub>O = 14.0 mm Hg

35

**Appendix B**

**Test Results**

**by**

**The Patrick Institute, Cincinnati, Ohio**

# **T P I** HE **PATRICK** **INSTITUTE**

President: Edward A. Patrick M.D., Ph.D, FACEP  
Fellow American College of Emergency Physicians  
Professor Purdue University (ret)  
Past President Systems Man & Cybermetrics Society of IEEE  
Author of ...  
*Fundamentals of Pattern Recognition*. Prentice Hall, 1972  
*Decision Analysis In Medicine*. CRC Press, 1979  
*Artificial Intelligence with Statistical Pattern Recognition*. Prentice Hall, 1986  
*Tomorrows American (chapter)*. Oxford Press, 1977

Individualized Outcome Analysis™  
Consult®  
The Outcome Advisor®

December 23, 1994

Mr. Wayne Whitbeck  
Precision Life Saving Products Inc.  
4444 Fieldgate Drive, Unit 15  
Mississauga, Canada L4W4TG

Fax 905 625 8947

Dear Mr. Whitbeck:

PATRICK ENERGY

What follows is our evaluation of the *Quick Air Choke Reliever* using the PATRICK ENERGY defined in the appended Appendix B with references. Evaluation consisted of comparing the estimated PATRICK ENERGY developed by the manual abdominal thrust as described by Heimlich and Patrick vs the PATRICK ENERGY developed by the *Quick Air Choke Reliever*.

Generating the Record with Synchronization

Three adult females and three adult males served as both subjects and rescuers. Body type ranged from thin to slightly overweight. Three positions were investigated: rescuer - standing, self - standing, and rescuer - supine. A case record was generated for each subject. Two records may be generated for the same subject but with different rescuers on different days.

It was decided to synchronize the initiation of the thrust by instructing the subject as follows: "breath in-and-out while relaxing, now take a deep breath - hold it." Telling the subject to "hold it" occurred when the subject and/or breathing pattern on the computer screen was observed at the end of inspiration.

Average (sample mean) PATRICK ENERGY

The sample mean is an unbiased, consistent statistic with relative significance for small sample size. Appropriately it is used here to compare the PATRICK ENERGY developed using the

manual method versus the device. The results, presented in Table 1, include the number of times the PATRICK ENERGY for the device exceeded that for the manual method. Results for each record are presented in the tables "PLSP Choking Device Results."

Table 1: Average (sample mean) PATRICK ENERGY

manual	device	ratio	# of times device energy > manual energy
<b>Rescuer - standing</b>			
991/9 = 110	1508/9 = 168	168/110 = 1.52	7/9
<b>Self - standing</b>			
1931/11 = 267	3230/11 = 294	3230/1931=1.10	7/11
<b>Rescuer - Supine</b>			
511/6 = 85	783/6 = 131	131/85 = 1.55	5/6

#### Complications

One report the device was too hard causing some pain.

One report that the device was awkward for the supine position and the handles are too close to the body.

One incident of pain in the xphi-sternum with transient circulatory shock due to the device being applied too high.

For comparison, complications using the manual method are discussed in Appendix A.

Conclusions

The device is promising in terms of the PATRICK ENERGY it produces compared with that for the manual method. Since risk using the device appears to be no greater than for the manual method, it is reasonable that the device be used if independent outcome analysis accompanies use of the device. Records must be collected using a scientific feature list (see Appendix C) to permit evaluating treatment outcomes (including complications). Provision must be made for evaluating sequences of treatments.

Sincerely,



Edward A. Patrick M.D., Ph.D., FACEP  
President The Patrick Institute

eap:af

cc: Dr. Eric Spletzer  
Mr. Mike Koechlein







### **3. Human Factors Testing**

New information is provided to the FDA in the attached (Section 3) "Human Factors Evaluation of the QuickAir Choke Reliever". This information shows that:

- Subjects using the QACR and its associated proposed labeling performed better on the upright manikin, the supine manikin, the tall victim and on themselves.
- Landmarking on a 12-year-old male human "victim" showed that the number of skills performed correctly using the QACR was significantly greater than the average number of skills performed by the subjects using the conventional landmarking method.
- The time it took subjects to perform their first thrust on the upright manikin could not be statistically distinguished between those subjects who used the device and those who administered the unassisted abdominal thrust.
- Subjects who used the QACR rated it easier to use than subjects who used the unassisted Heimlich maneuver (without device).

NOTE: Labels included in the human factors testing report are un black and white, however, all of the artwork is in full color, and will be produced in color for the actual product release.

Outcome analysis of the marketed device as used by the public will be done for persons reporting on a choking emergency situation, both with and without the device (see original 510 k submission). This data will far exceed the sparse and purely anecdotal data, which currently exists in the literature. By means of this outcome analysis, credible scientific and statistically significant data can be sent to the FDA and the American Heart Association.

**Human Factors Evaluation  
of the  
Quick Air Choke Reliever**

**Precious Life Saving Products Inc.**

Mississauga, Ontario

January 17-20, 2000

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**ABSTRACT**

The central objective of this study was to evaluate whether the human factors involved in using a new Heimlich adjunct device, the Quick Air Choke Reliever (QACR), with proposed accompanying labeling, resulted in its being comparable to the Heimlich Maneuver (HM) in ease of use, effectiveness, and safety. The study was conducted over a four-day period at a large shopping mall near Toronto, Ontario. Subjects were recruited from throughout the mall on consecutive afternoon/evenings. Participants were taken to an "evaluation area" within a church located on the ground floor of the mall. There they completed a pre-evaluation questionnaire and were assigned an ID in the order of their arrival. Based on their ID they were assigned to one of two treatments (QACR or HM) and one of three conditions (booklet, poster, or QACR label). They participated in the evaluation by demonstrating abdominal thrusts either using QACR or using the traditional manual HM on upright (standing) and supine (lying down) manikins and by demonstrating landmarking and fist/device positioning on upright human victims. Trained evaluators assessed the subject's skills using reliable checklists and a device for monitoring expiratory force during a thrust delivered to a manikin; they also timed how long it took subjects to deliver the first abdominal thrust. Subjects then completed a post-evaluation questionnaire, received a monetary incentive. In general, subjects using QACR performed more skills correctly than subjects using HM. Specifically, subjects using QACR performed better on the upright manikin ( $p < 0.0005$ ), the supine manikin ( $p = 0.030$ ), the tall victim ( $p = 0.073$ ) and on themselves ( $p < 0.0005$ ). While the performance of QACR subjects and HM subjects could not be distinguished statistically for the short human victim ( $p = 0.501$ ), subjects in the QACR sample performed more skills correctly than subjects in the HM sample. The time it took subjects to perform their first thrust on the upright manikin also could not be statistically distinguished between the two groups, although in the samples, subjects using HM took about one second less. Finally, the expiratory pressure obtained on the upright manikin was statistically similar between the two treatments, although QACR subjects achieved a greater pressure than the HM subjects in the samples. Further, subjects who used QACR during the evaluation rated it easier to use than subjects who used HM ( $p = .002$ ). Subjects using QACR also were more confident that they would know what to do in an emergency than subjects who used HM ( $p = .028$ ).

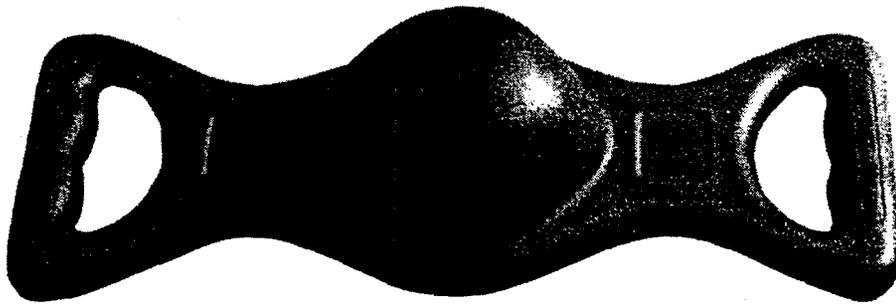
These results, together with the *in vitro* analysis, demonstrate that QACR is at least as safe and effective as HM, and that for upright victims and use on one's self, it is superior both in effectiveness and safety. While neither the QACR nor the HM can be performed consistently without error by untrained individuals, the results demonstrate that in the vast majority of cases, effective and safe thrusts can be delivered by either method. Further, the results seen here demonstrate far greater competency than seen in CPR training classes, in which about one out of five trainees cannot perform CPR that would be safe and effective even immediately after four hours of training.<sup>1, 2</sup>

1. Brennan RT, Braslow A. Skill mastery in cardiopulmonary resuscitation classes. *American Journal of Emergency Medicine* 1995;13:505-508.
2. Brennan RT, Braslow A. Skill mastery in public CPR classes. *American Journal of Emergency Medicine* 1998;16:653-657.

## **INTRODUCTION**

The accepted method of responding to a person who is choking is the Heimlich Maneuver (HM), developed by Dr. Henry Heimlich in 1974. This maneuver is performed by a rescuer standing behind the victim wrapping his/her arms around the victim's abdomen, forming a fist with thumb side toward victim's abdomen, with the other hand over this fist, then thrusting forcefully in an inward and slightly upward direction on the abdomen. The HM has been the standard adopted by the American Heart Association as the only appropriate response to a choking victim, both adult and child (over one year). Virtually every first-aid responder formally trained under a legitimate safety organization (e.g., American Red Cross) is taught the HM. In addition, many individuals, particularly those in the food service industry, are taught the HM outside of any other first aid techniques. Yet, there is some controversy as to the HM's effectiveness in relieving an airway obstruction for a variety of reasons (see *In Vitro Clinical Testing paper*). Additionally, given the nature of choking emergencies and their comparative rarity, it has been difficult to test the effectiveness of the HM in real situations.

The Quick Air Choke Reliever (QACR) was developed as an adjunct device to the HM. The device (Figure 1) is lightweight, includes a central compression unit shaped like a ball, and has handles on each side, which make it easy for the rescuer to grasp (see *In Vitro Clinical Testing paper* for a more complete description of QACR).



**Figure 1 Quick Air Choke Reliever (QACR)**

Though the QACR has been tested in vitro with small groups of subjects, this is the first report examining its performance, with intended labeling, when used by a large sample of participants. The purpose of the study was to determine if a broad and diverse population of subjects could relieve an airway obstruction using QACR, and its intended labeling, as effectively as they could with the traditionally accepted treatment, HM. Specifically, human factors are considered in assessing whether the choke reliever can be used by untrained laypersons even without prior instruction, but relying on the manufacturer's proposed labeling.

## **STUDY DESIGN**

### **Evaluators**

Study evaluators were recruited and trained by the study coordinators. Most were health-care providers: CPR instructors, ambulance drivers, and nurses. One study coordinator, a registered nurse, trained all evaluators to ensure consistency in their training. All evaluators were given an overview of the study and were then assigned to and trained for specific jobs. Recruiters were out in the mall signing up subjects for the study. Pre-evaluation and post-evaluation monitors were stationed at separate tables assisting participants with completing the questionnaires. Monitors were also responsible for preventing subjects who were waiting to enter the testing area from interacting with those who had already completed testing. Raters were stationed throughout the three testing stations and were trained to read the scripted instructions to participants; to rate their performance based on a skill checklist: to start and stop the stopwatch; to read the pressure gauge on the upright manikin; to move participants through all three first aid stations; and complete all skill checklists and return them to the post-test area. In addition, raters were expected to have all required materials (poster or booklet, and/or QACR and device label) available at the first aid table specific to the subjects ID as indicated by a master list. Finally, raters were responsible to see that manikins were functioning properly and that video cameras were running. All evaluators were trained to be able to answer questions and to provide feedback in such a way so as to not prompt or bias the participant. For example, when a participant asked a rater, "Did I do it right?" The rater was to respond, "You did fine." If a participant asked, "What should I do now?" the rater would respond, "Just do what you would do in an actual emergency."

### **Setting and recruitment of subjects**

Subjects were recruited within a large and popular mall near Toronto, Canada. Recruiters "intercepted" mall patrons and requested their participation in the study for a small monetary incentive. Recruiters were trained to describe the study in ways that would not bias the participants through a mechanism such as "hypothesis guessing." Recruiters were both male and female and maintained a professional appearance. Subjects were led to a facility that is used by a religious organization, which worked to offset apprehensions some may have had about going to an enclosed space with a stranger.

### **Pre-evaluation questionnaire and informed consent**

Upon arrival the subjects were issued an identification number (ID), which was copied onto all forms associated with that subject. Participants were instructed to fill out a brief questionnaire which elicited basic demographic information such as birth year, gender, level of education, and previous general first aid, first aid for choking, or CPR training (see Appendices). Monitors were available to assist study participants in completing the pre-evaluation questionnaire. The questionnaire also contained an informed consent statement. The statement explained that a

minimal amount of physical exertion would be required in the "evaluation" and urged people who might not be able to participate for whatever reason to opt out of the study. It explained that participants would be exposed to new methods or devices which may or may not be effective in first aid for choking. The consent form explained that all evaluations would be videotaped for research purposes only and not shown publicly or distributed. Subjects were informed they had no obligation to complete the evaluation and that they could stop at any time.

### **Participant assignment to treatment and condition**

This study was a randomized controlled trial (although systematic assignment, a substitute for true random assignment was used). Once subjects were issued an ID, participants were then systematically assigned a treatment and a condition. The two treatments were: HM (without the use of QACR), or QACR (HM using QACR). Within those treatments, subjects were also assigned a particular condition. For HM there were two possible conditions: (1) instruction by poster or (2) booklet. For QACR there were three such conditions: (1) instruction by poster, (2) booklet, or (3) device label. The booklet and poster demonstrated abdominal thrusts by both HM and QACR. Thus, the same booklet and poster were used regardless of the treatment. Treatment type (HM vs. QACR) and condition (poster, booklet and label for QACR) had been systematically assigned to ID numbers a priori and several copies of a "master list" were produced. For example, subjects with ID 1 and 2 were assigned to be evaluated on QACR, using the poster as the method of instruction. ID 3 and 4 were evaluated on QACR, using the booklet as the method of instruction. ID 5 and 6 were evaluated on QACR, using the label as the method of instruction. ID 7 was assigned to be evaluated on HM, using the poster as the method of instruction. ID 8 was evaluated on HM, using the booklet as the method of instruction. After each group of 8 subjects the assignment pattern repeats. (A sample page from the master list is in Appendices)

Subjects assigned to a treatment demonstrated that treatment through the evaluation (i.e., no subjects were exposed to both HM and QACR). The distribution of three QACR subjects to each HM subject was intentional, because a central concern of the study was to be able to differentiate any differences between subjects using each of the three QACR conditions. For a target sample of 150, this strategy would yield approximately 38 subjects using the HM, which we deemed sufficient for comparisons between the treatments. Systematic assignment is generally considered superior (except in cases where there might be some periodic structure to the sample frame, which did not exist in this case) to random assignment, particularly when the samples are small, as it achieves an exact distribution of conditions and treatments. Not only did the systematic assignment result in attainment of the desired sample sizes, but it ensured for example that the treatments and conditions were assigned evenly across times of day, which in a public mall are associated with shifting demographics.

## Procedures and Materials

The testing area was set up in one room broken down into three separate "first-aid stations" by using portable wall partitions. The first station contained an upright Laerdal CPR/Obstructed Airway manikin of about 5' 6". This manikin was intubated and connected to a pressure sensing (pressure manometer model #55-4700, Diemolding Healthcare Division), that would measure maximum expiratory force. The second station, located in a separate room, contained a supine manikin (without any kind of sensing mechanism). The third station consisted of a human victim, or in some cases, two human victims of various sizes: short victim (less than 5'5"), tall victim (greater than 5'9"), large girth victim (victim's abdomen was such that it would be difficult for an average adult to effectively position self to perform HM). Participants would be evaluated on different human "types" (short, tall, large girth), determined only by the availability of the "victims." Each participant, regardless of condition or treatment, was guided through each station, performing the HM either traditionally, that is without any device, or with QACR. Two stationary video cameras were positioned in the testing area. One camera recorded all activity at the first station. It recorded the subject being oriented by the rater, approaching the first aid table and reading the instructions available on poster, booklet, or label, and then taking action to relieve the airway obstruction on the upright manikin. The second video camera recorded the subject at either the second or third station. Since only two cameras were available for the study, it was moved periodically between the second and third stations. The primary purpose of the taping is to inform future studies, such as miscue analysis, that may be of value in documenting shortcomings of both methods.

The instructional materials included a poster, booklet, and label. Each gave written as well as pictorial instructions regarding how to perform the abdominal thrusts with QACR and without it (HM) on the upright victim, supine victim, and self. The label provided very few written details and contained two small black and white line drawings, which were also instructional; additionally the handles of the device were labeled to help in orienting the device properly. The booklet was a mock up consisting only of covers displaying instructions for the HM and QACR; the feature of having the instructions on the cover of the booklet will be carried over to production booklets (an earlier prototype complete booklet could not be used in this evaluation, due to changes in the instructions for locating one's hands for HM by the American Heart Association.) The instructions on the booklet contained a few written instructions and a few instructional photographs which were large and in color. The poster was very detailed, contained line drawings, and was printed in black, white and red, a motif commonly used for similar emergency posters. See appendices for proposed labeling.

After completing the pre-evaluation questionnaire, each participant was led into the "testing" area individually by one of the monitors. The participant was seated at the first station while a rater read a script (see Appendices) of instructions briefly explaining what would be expected of the participant. The rater read the scripted instructions in order to ensure that each participant received the instructions in exactly the same manner. Participants were given the opportunity to ask questions during the scripted instructions, but raters could only reiterate or clarify instructions. The script explains that the study compares several methods of first aid for someone who is choking and that people are needed to participate in order to determine if those

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methods are easy to understand and perform. Next, it explains that the participant will be asked to take action to save the life of someone who is choking and that he or she will start with the manikin who is standing up. The script also tells the participant that no questions will be answered once the participant begins to take action, and that he or she should do his or her best to save the choking victim. This is an important difference from "testing" protocols used by the American Heart Association and other organizations that prompt the subjects during skill performance. Such prompting, however neutral it is intended to be, may have the effect of "coaching" participants who are unsure what action to take. It urges the participant to take action as quickly as possible and to continue until told by the rater to stop. Once the subject was comfortable and indicated a readiness to begin, the rater read the final scripted instructions (note: "using the Choke Reliever" is optional; and only read to subjects assigned to the treatment):

*The victim is choking, and cannot cough, speak or breathe. Someone else has already called 911. Go to the first aid table, and when you are ready, begin by following the instructions for abdominal thrusts /using the choke reliever/. Keep going until I tell you to stop.*

The rater showed the participant a table that contained the poster or booklet or device label and the choke reliever, if applicable. The rater pointed to a table and stated "that is the first aid table," to ensure that participants were directed appropriately to all the materials needed. At this point the subject was expected to begin caring for the choking victim as directed by the condition.

Once the rater finished reading the script, the rater started a stopwatch, observed the skills of the participant and stopped the stopwatch once the participant completed one thrust. When the participant finished the skill, the rater completed the skill checklist, recorded the time in minutes and seconds taken to read the poster/booklet/label and to deliver a thrust (with or without the use of QACR), and recorded the maximum pressure attained according to the pressure gauge (in cm of water).

At the second station, participants were read another script directing them to perform the same skills on a supine victim. The script asked the participant to, "Do the thrusts on a person who is lying down using the manikin on the floor." They were allowed to refer to the poster/booklet/label if they desired. The participants were not timed at this station. Additionally, no pressure sensor was available in the manikin, and therefore pressure was not measured.

At the third station, participants were read a script directing them to perform the same skills on a human victim and/or themselves. The script asked the participant to, "Demonstrate how you would position yourself/hands/device; on /this person/yourself. Show me how you would position yourself, but don't really perform any actual thrusts." Each participant was cued several times at this station not to perform thrusts on the human victim (so as to ensure the safety of the human victim). Participants were not timed at the third station, nor was any pressure recorded. Depending on the volunteer victims available, the human victim may have been short, tall, or large girth. In some cases the subjects also demonstrated how they would do a thrust only on themselves.

### **Performance Measures**

Each participant was evaluated by the rater using uniform skill checklists. These check lists were designed to be similar to check lists used in research on cardiopulmonary resuscitation<sup>3</sup> that have been shown to be valid and reliable. They were adapted for use with choking victims using definitions from the American Heart Association Guidelines. The checklist was very specific and was easy to interpret. Although the skills tended to be similar, each treatment had its own checklists, and the skill checklists for human victims were specific to the characteristics of the volunteer. There is also a space on the checklist for the standing manikin station where the rater would document the time the participant took from the time the verbal instructions ended to the time the participant performed one thrust on the upright manikin. There was another space for the rater to document pressure attained as recorded by the pressure gauge. During training, evaluators worked alongside an experienced evaluator and practiced filling out a checklist. Until the evaluators were fully trained, only the checklist completed by the experienced evaluator was used. At several points during the study when an experienced evaluator was available, she completed a special second rater version of the checklist to be subsequently analyzed in assessing the interrater reliability of the checklists. Samples of the checklists are attached in appendices.

The beginning of the first checklist (standing manikin contains three items that are precursors to performing rescue measures: going to the first aid station, reading the booklet, poster, or label, and taking the Choke Reliever—this last step was not assessed on HM subjects. The next seven items on the checklist were the steps for performing abdominal thrusts, including: (1) subject standing behind manikin; (2) placing Choke Reliever in front of manikin, correctly oriented; (3) above the navel; (4) below the sternum; (5) on the midline; (6) grasping the choke reliever with two hands; (7) giving an abdominal thrust. The instructions for subjects performing the HM on the standing manikin, differed in items 2 (subject places fist in front of manikin, correctly oriented) and 6 (subject grasps fist with opposite hand).

The instructions for the supine manikin had 7 similar skills: (1) subject straddling manikin; (2) placing Choke Reliever on manikin's abdomen, correctly oriented; (3) above the navel; (4) at least 2cm below the breastbone; (5) on midline; (6) both hands on Choke Reliever; (7) giving one thrust. Again the skills 2 (subject places heel of hand on manikin's abdomen) and 6 (subject places opposite hand on top of first hand) varied for subjects performing HM. Checklists for human victims (both QACR and HM) were similar to the standing manikin checklist, but the thrust step was eliminated.

For each of the skills (standing manikin, supine manikin, standing human victims, and self) skill scores were created by summing the individual skill items. This resulted in 7-point scales for the manikin skills, 6-point scales for the human victims, and a 5-point scale for the self-treatment.

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3. Brennan RT, Braslow A, Batcheller AM, Kaye W. A reliable and valid method for evaluating cardiopulmonary resuscitation training outcomes. *Resuscitation* 1996;32:85-93.

### **Post-Evaluation Questionnaire**

Once the participant completed all three testing stations he or she was escorted to the post-evaluation area. Here, the participant would complete one of two questionnaires (for HM or QACR), depending on which treatment the participant was assigned (see Appendices). The questionnaire asked five questions specific to the participant's experiences with either the HM or QACR. First the participant was asked to rate (by checking a box) the ease of use of the HM or QACR on a four-point scale as one of the following: very easy, fairly easy, fairly difficult, or very difficult. Second, the participant was asked to rate (again, by checking a box) on a three-point scale his or her confidence level with regard to using the HM or QACR in a real choking emergency as one of the following: very confident, somewhat confident, or not at all confident. Third, the participant was asked his or her height and weight, to help the researchers to understand how the HM or QACR works for people of all different sizes. Fourth, the participant was asked to check which language he or she knows best: English or other. Finally, the fifth question asked for participant comments regarding the treatment (HM or QACR) and the condition (poster, booklet or label).

**RESULTS**

**Subject characteristics**

As described previously, demographic data were collected about subjects. 153 people participated in the study. Table 1 displays the overall composition of the sample for each of the binary variables.

**Table 1 - Subject Characteristics**

Trait	Yes	No	Total (n)	Percentage Yes
Female	76	76	152	50.0%
CPR, first aid or choking training in past 3 years	45	108	153	29.4%
English as first language	120	32	152	78.9%

There was no statistical variation in the distribution of these characteristics by age. Chi-square tests were used to test for group differences on these variables. The percentages of these variables (gender, recent training, and English) for each group are displayed in Table 2.

**Table 2 - Subject characteristics by treatment and condition**

Trait	QACR poster	QACR booklet	QACR label	HM poster	HM booklet	p value
Female	39.5%	50.0%	52.6%	47.3%	68.4%	0.352
CPR, first aid or choking training in past 3 years	44.4%	22.6%	36.8%	26.3%	36.8%	0.427
English as first language	74.4%	81.5%	73.7%	84.2%	84.2%	0.812

The average age of study participants was 33.4 years, with 13.3 years of education, 69.0 inches tall and weighing 157.6 pounds. As seen in the table below, there was no statistically significant group differences in age, education, height and weight with respect to treatment (QACR or HM) and condition (poster, booklet, label). Table 3 displays the mean age, years of education, height and weight for each treatment group. Group differences were tested using ANOVA.

**Table 3 - Subject Characteristics by Treatment and Condition**

Trait	QACR poster	QACR booklet	QACR label	HM poster	HM booklet	p value
Age in Years	36.7	34.7	32.2	30.1	29.4	0.487
Education in Years	13.6	12.9	12.9	13.4	13.8	0.522
Height in inches	69.6	70.2	66.4	67.4	72.6	0.597
Weight in Pounds	161.4	157.9	158.5	148.6	157.1	0.843

**Interrater Reliability**

In addition to the trained raters, a second rater was available to evaluate performance on some skills in order to establish reliability; the number of instances in which the second rater was available varied by the skill as indicated in Table 4. Interrater reliability (IR) was calculated using the Pearson correlation (Table 4). These reliabilities fall into the range generally considered to be high and suitable for research purposes. They are similar to (and in some cases exceed) the interrater reliabilities of the CPR skill checklists from which they were derived.<sup>3</sup>

**Table 4 - Interrater Reliability**

	Standing Manikin	Supine Manikin	Short Victim	Tall Victim	Seconds recorded from stopwatch	Pressure recorded from gauge
Number of Subjects	30	84	13	6	29	29
Reliability (Pearson Correlation)	0.816	0.890	0.719	1.000	0.965	0.998

**Skill Performance**

The analysis of skill outcomes was to determine if within each treatment the condition (booklet, poster, or label) was related to the results. Although the systematic assignment of subjects (a proxy for random assignments) allows for the assumption that the groups will be equal with regard to subject composition, we chose to use ANCOVA (analysis of covariance) to allow the analyses to be controlled for several subject background characteristics (height, age, education, gender, first language, and training in first aid for choking victims within the last three years). Taking this additional step reduces the chance for bias that might be introduced by differences between groups in the sample (weight, another key characteristic of subjects was omitted due to a number of missing values). Another advantage of ANCOVA is that it provides “adjusted least

squares means”; these adjust the observed means for differences in subject characteristics and allow for easy comparisons across groups.

Table 5 displays the results for QACR conditions (booklet, poster, or label only). ANCOVA results show that there are no significant differences between the conditions for the seven skill outcomes evaluated.

**Table 5 - Skill performance score by condition type for QACR**  
(Adjusted least squares means)

Skill type	Poster	Booklet	Label	n	p-value
Upright (range 0-7)	5.85	5.92	5.89	110	0.971
Supine (range 0-7)	4.70	5.41	5.22	110	0.144
Short (range 0-6)	5.39	5.44	5.01	35	0.691
Tall (range 0-6)	5.18	4.92	5.23	65	0.667
Self (range 0-5)	4.44	4.67	4.40	66	0.605
Seconds	51.43	42.12	45.95	109	0.548
Pressure (cm of water)	15.59	13.63	13.35	109	0.784

Table 6 displays the results for the two HM conditions (booklet or poster). Again ANCOVA results show that there are no significant differences between the two groups.

**Table 6 - Skill performance score by condition type for HM**

Skill Type	Poster	Booklet	n	p-value
Upright (range 0-7)	4.59	5.04	38	0.377
Supine (range 0-7)	4.05	4.84	38	0.281
Short (range 0-6)	4.78	5.47	11	0.677
Tall (range 0-6)	4.45	4.70	26	0.652
Self (range 0-5)	3.81	3.27	26	0.392
Seconds	50.56	37.66	38	0.143
Pressure (cm of water)	10.78	12.17	38	0.730

Given that there were no differences in skill outcomes associated with condition for either QACR or HM, we then compared the results for all QACR subjects with those for HM subjects. Again, ANCOVA was employed to control the analyses for differences in background variables. Participants performed most skills correctly more often when using QACR than when using the HM alone. In fact, the only instance where the observed value for HM subjects was more favorable than for QACR subjects was in the number of seconds to first thrust, where HM subjects took about 1 second less than QACR subjects. For the upright manikin, subjects using QACR performed nearly 6 of 7 skills correctly versus fewer than 5 for subjects using HM. This

difference was significant at  $< .0005$ . The observed difference between QACR and HM for the supine manikin of about .7 skills was also significant ( $p = .030$ ). Although there is an observed difference in performance between HM and QACR for the short human victim the difference could not be distinguished from 0 ( $p = .501$ ). The observed difference between QACR and HM of about one half a skill on the tall human victim was of borderline significance ( $p = .073$ ). When using the device on oneself, subjects using QACR performed nearly all of the five skills correctly on the average, versus fewer than four skills performed correctly by subjects performing HM; this difference was significant ( $p < .0005$ ).

Neither the difference in time to first thrust nor pressure attained differed significantly between subjects using QACR and subjects using HM.

**Table 7 - Skill Performance by Treatment Type**

SKILL	QACR	HM	n	p-value
Upright (range 0-7)	5.93	4.70	148	0.000
Supine (range 0-7)	5.13	4.39	148	0.030
Short (range 0-6)	5.31	5.00	46	0.501
Tall (range 0-6)	5.10	4.59	91	0.073
Self (range 0-5)	4.49	3.56	92	0.000
Seconds	46.21	45.09	147	0.860
Pressure (cm of water)	14.33	11.11	147	0.224

Finally, for ease of comparison across treatments and conditions we ran ANCOVA models including both treatments and all conditions (Table 8). These results are similar to the results above. Using the adjusted least square means from this analysis we created plots of the results affording a visual comparison of the treatments and conditions on the seven skill outcomes.

**Table 8 - Skill Performance by Condition and Treatment Type**

SKILL	QACR poster	QACR booklet	QACR label	HM poster	HM booklet	p-value
Upright	5.872	6.002	5.910	4.437	4.979	0.000
Supine	4.690	5.466	5.222	3.982	4.819	0.035
Short	5.393	5.514	5.011	4.769	5.300	0.795
Tall □	5.055	5.043	5.190	4.476	4.713	0.459
Self	4.420	4.690	4.392	3.763	3.331	0.005
Seconds	50.993	42.245	45.467	51.688	38.083	0.581
Pressure	15.546	14.030	13.382	10.343	11.867	0.730

Figure 2 displays the adjusted least square means for the scores on the upright manikin skills (range 0-7). There is a perceptible difference between the three QACR conditions and the HM

conditions. While QACR results appear little affected by the three conditions, there is a perceptible difference in outcome for HM favoring the booklet condition. Figure 3 displays the adjusted least square means for the skill scores on the supine manikin. Here it is not so easy to discern a difference in performance for the two treatments, and while not statistically significant, differences among QACR treatment conditions are more strongly suggested than in Figure 2. In Figure 4 one sees that the differences among the treatments and conditions are practically indiscernible for skill performed on the "short" human victim. Figure 5 shows a weak, but clear trend in which subjects using QACR perform more skills correctly than subjects using HM. Finally, Figure 6 displays the adjusted least square mean skill scores for subjects performing abdominal thrusts on themselves. Here it is clear that the subjects using QACR perform more of the five skills correctly than the subjects using HM.

In addition to the analyses already described, we conducted a small pilot investigation using a male victim, 12 years old, 4' 10" tall and 85 pounds. Fifteen subjects were asked to demonstrate either QACR or HM on the boy. There was insufficient data to explore the differences within each treatment; however, an ANCOVA analysis revealed that the average number of skills performed correctly by the QACR subjects (adjusted least squares mean = 5.43) was significantly greater than ( $p = 0.038$ ) the average number of skills performed correctly by the HM subjects (adjusted least squares mean = 3.31). Figure 7 displays the results.

**Confidence and Ease of Use**

On the post-evaluation questionnaire, participants were asked to rate how easy QACR or the HM was to use (with 1 being very difficult and 4 being very easy). Participants were also asked to rate their confidence level with regard to using QACR or HM in a real choking emergency. Table 8 illustrates these results:

**Table 8 - Ease and Confidence with Regard to QACR and HM**

	QACR	HM	n	p-value
Ease of Use (1-4)	3.5	3.0	150.0	0.002
Confidence (1-3)	2.5	2.2	150.0	0.028

QACR was rated easier to use than the HM. Additionally, the level of confidence felt by participants is greater with QACR than it is with the HM alone.

## DISCUSSION

The demographics of the participant pool were encouraging in the way that a good percentage (21%), did not consider English the language that they knew best. Despite all the written and verbal instructions in English, many apparently were able to pick up enough to perform well using QACR. Perhaps the pictures appearing on the poster, booklet and label were adequate. There were also an even number of males and females. And only 29% of participants had recent (defined as having taken place within three years of the date of testing) first aid training (a lower percentage than other similar studies).<sup>4,5</sup>

QACR not only performed as well as the HM, it consistently performed better, especially when looking at performance on standing, supine, self, and tall victims. When comparing its use with short victims, there was no statistical difference between QACR and the HM. But as evidenced in Table 4, QACR does outperform HM by a small margin. This is true also for the amount of pressure exerted to an upright victim's abdomen. Participants did take a slightly longer time (one second) to read instructions and then carry out abdominal thrusts on the upright manikin. However, this difference is not statistically significant. This could be attributed to the fact that when QACR is used in a choking emergency (or in this simulated evaluation), the participant needs to get and pick up QACR, a step not required in the HM.

It was interesting that the HM did not fare as well as QACR for several skills. This is surprising as many participants would have been exposed as some point to the HM, either in previous training, through the media, through conversation, etc. None of the participants were previously exposed to QACR, so it was not expected to perform as well as the HM.

QACR performed best in the situations in which it is intended to be used: on victims who are upright and on oneself. Though it performed well on the supine victim, this was not its original intended use.

The most interesting results of this study can be found in participants' ratings of ease and confidence. Participants rated QACR on average, somewhere between fairly easy and very easy to use (3.4/4.0). They also rated confidence between somewhat and very confident (2.5/3.0). On the other hand, the HM was rated fairly easy (3.0) and closer to somewhat confident (2.2/3.0). In previous studies of CPR training using this same measure,<sup>4,5,6</sup> level of confidence did not in any way correspond to performance or competence, and did not differ between radically different training methods (i.e., classroom instruction versus video self-instruction). Here, it can be concluded that confidence and ease of use correspond to performance outcomes. In a real emergency this is an important factor because rescuers are likely to respond if they feel confident

4. Braslow A, Brennan RT, Newman MM, Bircher NG, Batcheller AM, Kaye W. CPR training without an instructor: development and evaluation of a video self-instructional system for effective performance of cardiopulmonary resuscitation. *Resuscitation* 1997;34:207-220.
5. Batcheller A, Brennan RT, Braslow A, Urrutia A, Kaye W. Cardiopulmonary resuscitation (CPR) performance of subjects over forty is better following half-hour video self-instruction compared to traditional four-hour classroom training. *Resuscitation* 2000; 43:101-110
6. Brennan RT, Braslow A. Are we training the right people yet? A survey of participants in public cardiopulmonary resuscitation classes. *Resuscitation*, 1998;37:21-25.

in their equipment and abilities. In the case of a choking emergency, if a rescuer feels confident using QACR, he or she is more likely to take action. And that action may result in a better outcome for the victim, (based on better skill performance as demonstrated in this study and in superior physiological outcomes as demonstrated in the in vitro study) than if the HM only was used.

## **LIMITATIONS AND FUTURE RESEARCH**

The average age of participants was approximately 32 years, yet older people are at greater risk not only of choking, but also of being alone when they choke, with no one to assist them. An older subject pool might reveal different results when comparing QACR to the HM.

Due to the limited number of participants who performed QACR or HM skills on the short and large-girth victims (not included in the present analyses due to the low number of subjects), the results are rather inconclusive. Future studies could focus on this group of victims, especially the large-girth victim, as it is often very difficult to perform the HM on them as sometimes the rescuers arms are unable to reach the around the victim's abdomen.

Finally, it was difficult to gather accurate information regarding height, weight and birth year. Participants tended to overestimate height and underestimate weight and age. So it is likely that the average participant is slightly less than 5'9", slightly greater than 156 pounds and slightly older than 32 years of age.

The results of this human factors evaluation are extremely promising, and demonstrate that QACR can be used at least as safely and that it will be at least as effective as the HM. Indeed, the these results and the in vitro results strongly suggest that in emergencies involving an upright victim or one's self, QACR should be both safer and more effective than HM. This study, including its data collection methods is easily replicable. Thus, future research can be undertaken to study special populations and to strive to improve text support and labeling for both QACR and HM.

Figure 2 - Adjusted least squares means for upright manikin skills

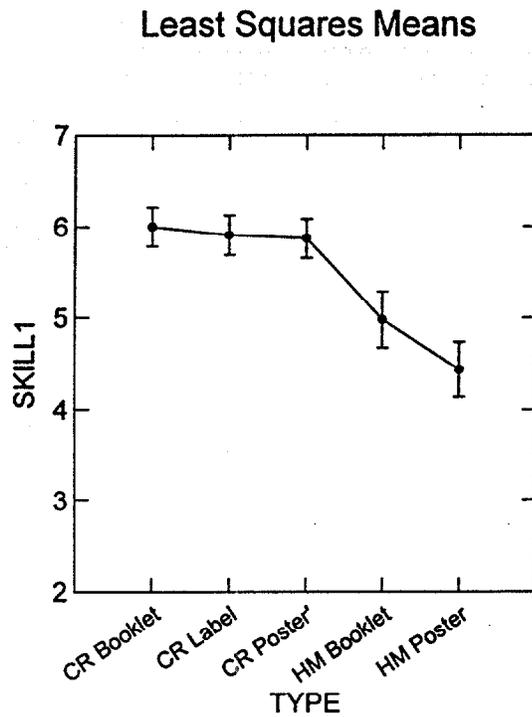


Figure 3 - Adjusted least squares means for supine manikin skills.

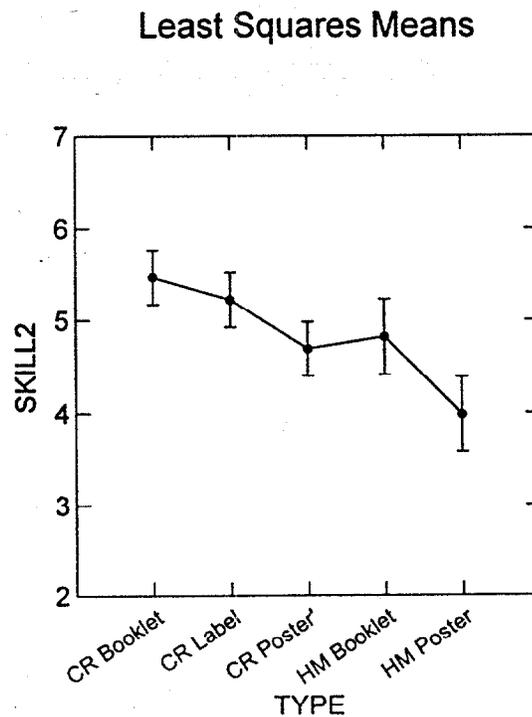


Figure 4 - Adjusted least squares means for "short" human victim skills

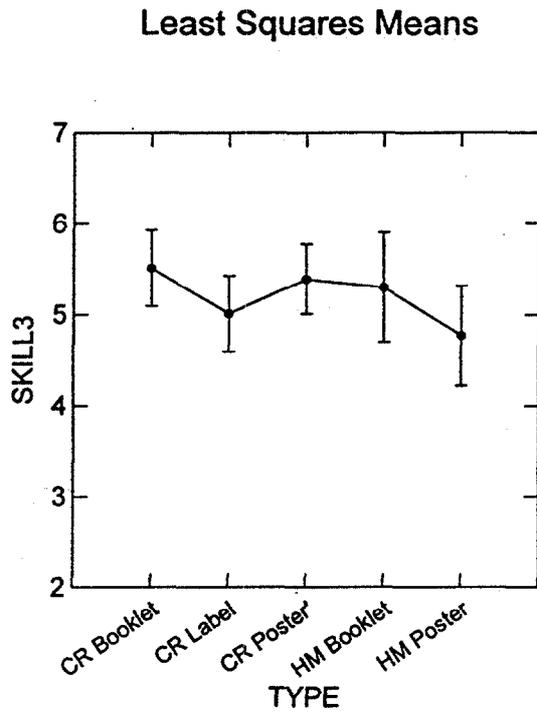


Figure 5 - Adjusted least squares means for "tall" human victim skills

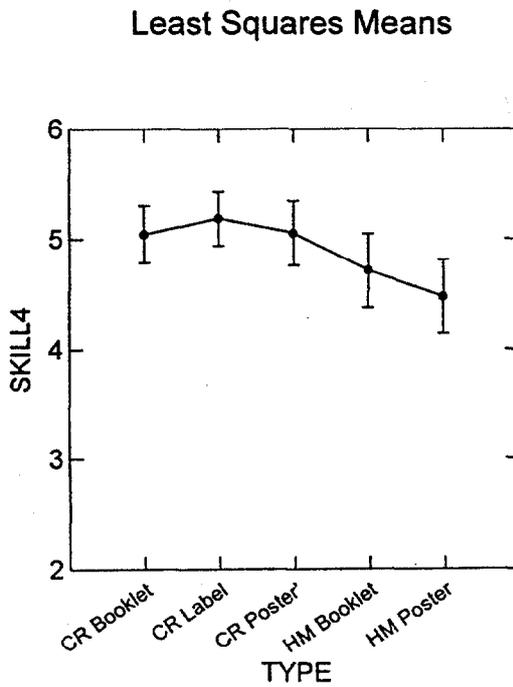


Figure 6 - Adjusted Least Squares Means for Skills Performed on Self

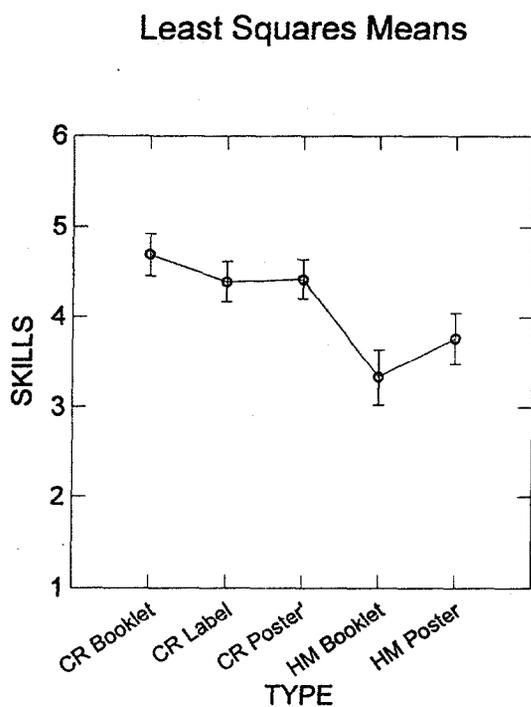
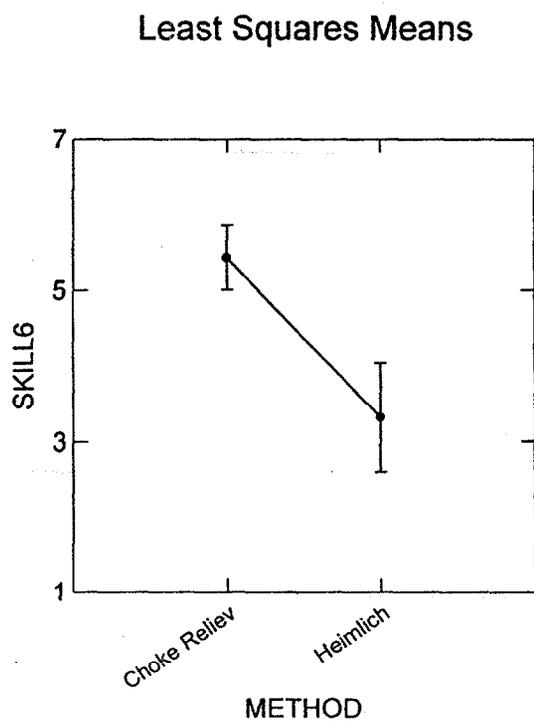


Figure 7 - Adjusted Least Squares Means for 12 Year -old Human Victim Skills



**Appendices**

- I. Manikin skill checklist–Choke Reliever
- II. Manikin skill checklist – Heimlich
- III. Human skill checklist – Choke Reliever
- IV. Human skill checklist – Heimlich
- V. Evaluator Script – Choke Reliever
- VI. Evaluator Script – Heimlich
- VII. Master list (sample page)
- VIII. Labels used in this human factors test

# I. MANIKIN SKILL CHECKLIST- CHOKE RELIEVER

ID# ID \_\_\_\_\_ First name FIRSTS\$ \_\_\_\_\_ Last name LAST\$ \_\_\_\_\_

Evaluation type: TYPE \_\_\_\_\_ Poster 1 \_\_\_\_\_ Booklet 2 \_\_\_\_\_ Label Only 3

***THIS PERSON IS CHOKING AND CANNOT SPEAK, COUGH, OR BREATHE. THE PERSON NEEDS IMMEDIATE FIRST AID. SOMEONE ELSE IS CALLING 911. GO TO THE FIRST AID STATION, AND WHEN YOU ARE READY, BEGIN BY FOLLOWING THE INSTRUCTIONS FOR ABDOMINAL THRUSTS USING THE CHOKE RELIEVER. KEEP GOING UNTIL I TELL YOU TO STOP.***

## **BEGIN STOPWATCH TIMING**

- \_\_\_\_\_ Subject goes to first aid station STATION1
- \_\_\_\_\_ Subject reads booklet, poster, and/or label (any one of the three) READS1
- \_\_\_\_\_ Subject takes Choke Reliever RELIEVER1
- \_\_\_\_\_ Subject stands behind manikin BEHIND1
- \_\_\_\_\_ Subject places Choke Reliever in front of manikin, correctly oriented ORIENT1
- \_\_\_\_\_ Choke Reliever is above the navel NAVEL1
- \_\_\_\_\_ Choke Reliever is at least 2cm below the breastbone STERNUM1
- \_\_\_\_\_ Choke Reliever is positioned on midline MIDLINE1
- \_\_\_\_\_ Subject grasps Choke Reliever with both hands BOTH1
- \_\_\_\_\_ Subject gives one thrust THRUST1 **STOP THE STOPWATCH**

### **TELL THE SUBJECT TO STOP**

- \_\_\_\_\_ minutes MINS1 and \_\_\_\_\_ seconds SECS1 **RECORD STOPWATCH TIME**
- \_\_\_\_\_ Maximum pressure PRESSURE1 **RECORD MAXIMUM PRESSURE AND RESET**

***NOW I WOULD LIKE YOU TO TAKE THE CHOKE RELIEVER AND DEMONSTRATE HOW YOU WOULD DO THE THRUSTS ON A PERSON WHO IS LYING DOWN. YOU WILL BE USING THE MANIKIN ON THE FLOOR. KEEP GOING UNTIL I TELL YOU TO STOP.***

- \_\_\_\_\_ Subject straddles manikin STRADDLE2
- \_\_\_\_\_ Subject places Choke Reliever on manikin's abdomen, correctly oriented ORIENT2
- \_\_\_\_\_ Choke Reliever is above the navel NAVEL2
- \_\_\_\_\_ Choke Reliever is at least 2cm below the breastbone STERNUM2
- \_\_\_\_\_ Choke Reliever is positioned on midline MIDLINE2
- \_\_\_\_\_ Subject places both hands on Choke Reliever BOTH2
- \_\_\_\_\_ Subject gives one thrust THRUST2

### **TELL THE SUBJECT TO STOP**

## II. MANIKIN SKILL CHECKLIST- HEIMLICH

ID# ID \_\_\_\_\_ First name FIRST\$ \_\_\_\_\_ Last name LAST\$ \_\_\_\_\_

Evaluation type: TYPE \_\_\_\_\_ Poster 4 \_\_\_\_\_ Booklet 5

***THIS PERSON IS CHOKING AND CANNOT SPEAK, COUGH, OR BREATHE. THE PERSON NEEDS IMMEDIATE FIRST AID. SOMEONE ELSE IS CALLING 911. GO TO THE FIRST AID STATION, AND WHEN YOU ARE READY, BEGIN BY FOLLOWING THE INSTRUCTIONS FOR ABDOMINAL THRUSTS. KEEP GOING UNTIL I TELL YOU TO STOP.***

### BEGIN STOPWATCH TIMING

\_\_\_\_\_ Subject goes to first aid station STATION1

\_\_\_\_\_ Subject reads booklet or poster READS1

blank Subject takes Choke Reliever RELIEVER1

\_\_\_\_\_ Subject stands behind manikin BEHIND1

\_\_\_\_\_ Subject places fist in front of manikin, correctly oriented ORIENT1

\_\_\_\_\_ Fist is above the navel NAVEL1

\_\_\_\_\_ Fist is at least 2cm below the breastbone STERNUM1

\_\_\_\_\_ Fist is positioned on midline MIDLINE1

\_\_\_\_\_ Subject grasps fist with opposite hand BOTH1

\_\_\_\_\_ Subject gives one thrust THRUST1 **STOP THE STOPWATCH**

### TELL THE SUBJECT TO STOP

\_\_\_\_\_ minutes MINS1 and \_\_\_\_\_ seconds SECS1 **RECORD STOPWATCH TIME**

\_\_\_\_\_ Maximum pressure PRESSURE1 **RECORD MAXIMUM PRESSURE AND RESET**

***NOW I WOULD LIKE YOU TO DEMONSTRATE HOW YOU WOULD DO THE THRUSTS ON A PERSON WHO IS LYING DOWN. YOU WILL BE USING THE MANIKIN ON THE FLOOR. KEEP GOING UNTIL I TELL YOU TO STOP.***

\_\_\_\_\_ Subject straddles manikin STRADDLE2

\_\_\_\_\_ Subject places heel of hand on manikin's abdomen ORIENT2

\_\_\_\_\_ Heel of hand is above the navel NAVEL2

\_\_\_\_\_ Heel of hand is at least 2cm below the breastbone STERNUM2

\_\_\_\_\_ Heel of hand is positioned on midline MIDLINE2

\_\_\_\_\_ Subject places opposite hand on top of first hand BOTH2

\_\_\_\_\_ Subject gives one thrust THRUST2

### TELL THE SUBJECT TO STOP

### III. HUMAN SKILL CHECKLIST-CHOKE RELIEVER

ID# ID \_\_\_\_\_ First name FIRST\$ \_\_\_\_\_ Last name LAST\$ \_\_\_\_\_

Evaluation type: TYPE \_\_\_\_\_ Poster 1 \_\_\_\_\_ Booklet 2 \_\_\_\_\_ Label Only 3

***NOW I WOULD LIKE YOU TO TAKE THE CHOKE RELIEVER AND DEMONSTRATE HOW YOU WOULD DO THE THRUSTS ON THIS PERSON. SHOW ME HOW YOU WOULD POSITION YOURSELF AND THE CHOKE RELIEVER, BUT DON'T PERFORM ANY ACTUAL THRUSTS.***

#### **VICTIM UNDER 165 cm (5' 5")**

\_\_\_\_\_ cm Height of victim in centimeters VHEIGHT3 RECORD VICTIM'S HEIGHT

\_\_\_\_\_ kg Weight of victim in kilograms VWEIGHT3 RECORD VICTIM'S WEIGHT

\_\_\_\_\_ Subject stands behind victim BEHIND3

\_\_\_\_\_ Subject places Choke Reliever in front of victim, correctly oriented ORIENT3

\_\_\_\_\_ Choke Reliever is above the navel NAVEL3

\_\_\_\_\_ Choke Reliever is at least 2cm below the breastbone STERNUM3

\_\_\_\_\_ Choke Reliever is positioned on midline MIDLINE3

\_\_\_\_\_ Subject grasps Choke Reliever with both hands BOTH3

***NOW CAN YOU SHOW ME HOW YOU WOULD USE THE CHOKE RELIEVER ON THIS PERSON? REMEMBER, DON'T DO ANY ACTUAL THRUSTS.***

#### **VICTIM OVER 175 cm (5' 9")**

\_\_\_\_\_ cm Height of victim in centimeters VHEIGHT4 RECORD VICTIM'S HEIGHT

\_\_\_\_\_ kg Weight of victim in kilograms VWEIGHT4 RECORD VICTIM'S WEIGHT

\_\_\_\_\_ Subject stands behind victim BEHIND4

\_\_\_\_\_ Subject places Choke Reliever in front of victim, correctly oriented ORIENT4

\_\_\_\_\_ Choke Reliever is above the navel NAVEL4

\_\_\_\_\_ Choke Reliever is at least 2cm below the breastbone STERNUM4

\_\_\_\_\_ Choke Reliever is positioned on midline MIDLINE4

\_\_\_\_\_ Subject grasps Choke Reliever with both hands BOTH4

***NOW WE WOULD LIKE YOU TO FILL OUT A VERY BRIEF QUESTIONNAIRE. WHEN YOU ARE DONE WITH THIS SURVEY, HAND IT IN AND YOU WILL GET YOUR \$5.***

**GIVE QUESTIONNAIRE TO SUBJECT WITH ID NUMBER ALREADY FILLED IN.**

## IV. HUMAN SKILL CHECKLIST-HEIMLICH

ID# ID \_\_\_\_\_ First name FIRST\$ \_\_\_\_\_ Last name LAST\$ \_\_\_\_\_

Evaluation type: TYPE \_\_\_\_\_ Poster 4 \_\_\_\_\_ Booklet 5

*NOW I WOULD LIKE YOU TO DEMONSTRATE HOW YOU WOULD DO THE THRUSTS ON THIS PERSON. SHOW ME HOW YOU WOULD POSITION YOURSELF AND YOUR HANDS, BUT DON'T PERFORM ANY ACTUAL THRUSTS.*

### VICTIM UNDER 165 cm (5' 5")

\_\_\_\_\_ cm Height of victim in centimeters VHEIGHT3 RECORD VICTIM'S HEIGHT

\_\_\_\_\_ kg Weight of victim in kilograms VWEIGHT3 RECORD VICTIM'S WEIGHT

\_\_\_\_\_ Subject stands behind victim BEHIND3

\_\_\_\_\_ Subject places fist in front of victim, correctly oriented ORIENT3

\_\_\_\_\_ Fist is above the navel NAVEL3

\_\_\_\_\_ Fist is at least 2cm below the breastbone STERNUM3

\_\_\_\_\_ Fist is positioned on midline MIDLINE3

\_\_\_\_\_ Subject places opposite hand on fist BOTH3

*NOW CAN YOU SHOW ME HOW YOU WOULD DO THRUSTS ON THIS PERSON ON THIS PERSON? REMEMBER, DON'T DO ANY ACTUAL THRUSTS.*

### VICTIM OVER 175 cm (5' 9")

\_\_\_\_\_ cm Height of victim in centimeters VHEIGHT4 RECORD VICTIM'S HEIGHT

\_\_\_\_\_ kg Weight of victim in kilograms VWEIGHT4 RECORD VICTIM'S WEIGHT

\_\_\_\_\_ Subject stands behind victim BEHIND4

\_\_\_\_\_ Subject places fist in front of victim, correctly oriented ORIENT4

\_\_\_\_\_ Fist is above the navel NAVEL4

\_\_\_\_\_ Fist is at least 2cm below the breastbone STERNUM4

\_\_\_\_\_ Fist is positioned on midline MIDLINE4

\_\_\_\_\_ Subject places opposite hand on fist BOTH4

*NOW WE WOULD LIKE YOU TO FILL OUT A VERY BRIEF QUESTIONNAIRE. WHEN YOU ARE DONE WITH THIS SURVEY, HAND IT IN AND YOU WILL GET YOUR \$5.*

GIVE QUESTIONNAIRE TO SUBJECT WITH ID NUMBER ALREADY FILLED IN.

## V. Evaluator Script—Choke Reliever

Before you begin, make sure that your stopwatch and the pressure sensor on the manikin are reset.

*We are in the process of evaluating and comparing several methods for doing first aid on someone who is choking. We need people like you to help us make sure that the methods are easy to understand and to perform.*

*Once I give you instructions, this will be a realistic emergency situation; you should take action to try to save the life of the person who is choking. Just like in a real choking emergency, time is of the essence, so you should take action as quickly as you can. We will start with this manikin that is standing up. It will represent someone who is choking.*

*You will be using a new device called the Choke Reliever. You can find out how to use it by using a poster/a booklet/the label. However, you will not be able to look at that until I tell you to start. Remember once I give you the final instructions you should take action as soon as you can.*

*When you are ready, I will give you some instructions about what to do. Once you start, I won't be able to answer any questions or help you figure out what to do.*

*If you make a mistake or forget to do something important, you should not stop. Just do your best to correct the error. You should continue doing what you would do in an actual emergency until I tell you to stop.*

*Do you have any questions before we start?*

If they ask any questions, you should only repeat the relevant instructions. If they ask questions about the technique, you should not provide any information. You may tell them:

*The poster/booklet/label will have all the information you will need to use the Choke Reliever.*

Once they indicate they are ready, you should ask them the following:

*Are you ready for me to read you the final instructions?*

When they indicate yes, you will read the final instructions on the "Manikin Skill Checklist."

You will start your stopwatch as soon as you finish reading the instructions on the checklist.

## VI. Evaluator Script – Heimlich

Before you begin, make sure that your stopwatch and the pressure sensor on the manikin are reset.

*We are in the process of evaluating and comparing several methods for doing first aid on someone who is choking. We need people like you to help us make sure that the methods are easy to understand and to perform.*

*Once I give you instructions, this will be a realistic emergency situation; you should take action to try to save the life of the person who is choking. Just like in a real choking emergency, time is of the essence, so you should take action as quickly as you can. We will start with this manikin that is standing up. It will represent someone who is choking.*

*You will be performing abdominal thrusts, sometimes called the Heimlich maneuver. You can find out how to do it, by using a poster/a booklet. You will not be able to look at that until I tell you to start. Remember once I give you the final instructions you should take action as soon as you can.*

*When you are ready, I will give you some instructions about what to do. Once you start, I won't be able to answer any questions or help you figure out what to do.*

*If you make a mistake or forget to do something important, you should not stop. Just do your best to correct the error. You should continue doing what you would do in an actual emergency until I tell you to stop.*

*Do you have any questions before we start?*

If they ask any questions, you should only repeat the relevant instructions. If they ask questions about the technique, you should not provide any information. You may tell them:

*The poster/booklet will have all the information you will need.*

Once they indicate they are ready, you should ask them the following:

*Are you ready for me to read you the final instructions?*

When they indicate yes, you will read the final instructions on the “Manikin Skill Checklist.”

**You will start your stopwatch as soon as you finish reading the instructions on the checklist.**

## VII. Master List

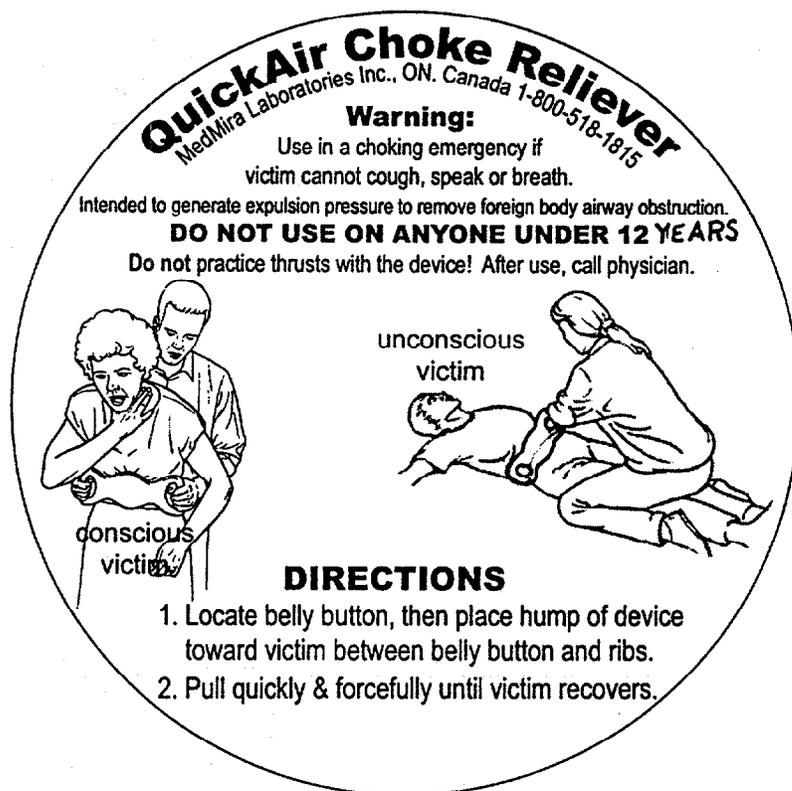
<b>ID#</b>	<b>Treatment</b>
1	Choke Reliever, poster
2	Choke Reliever, poster
3	Choke Reliever, booklet
4	Choke Reliever, booklet
5	Choke Reliever, label only
6	Choke Reliever, label only
7	Heimlich, poster
8	Heimlich, booklet
9	Choke Reliever, poster
10	Choke Reliever, poster
11	Choke Reliever, booklet
12	Choke Reliever, booklet
13	Choke Reliever, label only
14	Choke Reliever, label only
15	Heimlich, poster
16	Heimlich, booklet
17	Choke Reliever, poster
18	Choke Reliever, poster
19	Choke Reliever, booklet
20	Choke Reliever, booklet
21	Choke Reliever, label only
22	Choke Reliever, label only
23	Heimlich, poster
24	Heimlich, booklet
25	Choke Reliever, poster
26	Choke Reliever, poster
27	Choke Reliever, booklet
28	Choke Reliever, booklet
29	Choke Reliever, label only
30	Choke Reliever, label only
31	Heimlich, poster
32	Heimlich, booklet
etc., etc....	

## VIII. Labeling

### Device Label

Please note that the label design shows the "QuickAir Choke Reliever" in red type.

The words "DO NOT USE ON ANYONE UNDER 12 YEARS" is in red type.



## **VIII. Labeling (cont'd)**

### **Poster**

**Please note that the actual printed poster uses black and red to emphasize the following:**

- **“First Aid for Choking”**
- **“IF VICTIM BECOMES UNCONSCIOUS”**
- **“NOTE: Do not practice performing abdominal thrusts”**

# First Aid for Choking

The Choke Reliever is intended to be used in the event of choking to generate expulsion pressure for the removal of foreign body airway obstruction in victims 12 years or older.



Assess if Victim Can Speak, Cough or Breathe.



NO

YES

Continue to Monitor



## Perform Abdominal Thrusts



### Using Choke Reliever

Locate belly button, then place hump of device toward victim between belly button and ribs. Pull inward quickly and **forcefully** until victim recovers or becomes unconscious.

### Using Your Fist

Place your fist with thumb side against the abdomen between belly button and ribs. Grasp your fist with your other hand and pull inward with quickly and **forcefully** until victim recovers or becomes unconscious.



## IF THE VICTIM BECOMES UNCONSCIOUS



## Visually Search Mouth

- Position victim on his/her back, then send for emergency medical help, or call 911/"help".
- Hold the tongue with your thumb and grasp the chin with your fingers. Hold the jaw firmly. Lift the jaw.

