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# Summary Of Review Of Procurement Of Fort Totten Resuscitators

B-165631

Department of Defense

BY THE COMPTROLLER GENERAL  
OF THE UNITED STATES

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[090750]

JUNE 29, 1972



COMPTROLLER GENERAL OF THE UNITED STATES  
WASHINGTON, D.C. 20548

B-165631

JUN 29 1972

4 Dear Senator Pastore:

Reference is made to your letter of July 21, 1971, enclosing correspondence from Dr. Meyer Saklad concerning the procurement of Fort Totten resuscitators by the Department of Defense. Other requests for information on this procurement were received about the same time from several members of the Congress.

Enclosed are two copies of our report on the procurement of the Fort Totten resuscitator by the Department of Defense. We have not requested written comments from the Department of Defense on this report. The report is also being sent to the other members of the Congress and the medical professionals, who inquired about this matter, and to the Secretary of Defense.

We trust this information is responsive to your needs.

Sincerely yours,

A handwritten signature in cursive script that reads "James B. Stacks".

Comptroller General  
of the United States

Enclosures - 2

The Honorable John O. Pastore  
United States Senate



COMPTROLLER GENERAL OF THE UNITED STATES  
WASHINGTON, D.C. 20548

JUN 29 1972

B-165631

*cc* Dear Senator Spong:

Reference is made to your letter of June 25, 1971, in which you refer to a letter from Dr. John Q. Durfey to the Comptroller General protesting the procurement of the Fort Totten resuscitator by the Department of Defense. Other requests for information on this procurement were received about the same time from several members of the Congress.

Enclosed are two copies of our report on the procurement of the Fort Totten resuscitator by the Department of Defense. We have not requested written comments from the Department of Defense on this report. The report is also being sent to the other members of the Congress and the medical professionals, who inquired about this matter, and to the Secretary of Defense.

We trust this information is responsive to your needs.

Sincerely yours,

A handwritten signature in cursive script that reads "James B. Stacks".

Comptroller General  
of the United States

Enclosures - 2

The Honorable William B. Spong, Jr.  
United States Senate



COMPTROLLER GENERAL OF THE UNITED STATES  
WASHINGTON, D.C. 20548

JUN 29 1972

B-165631

C3 Dear Senator Brooke:

Reference is made to your letter of August 31, 1971, in which you referred to your correspondence with Mr. J. H. Emerson concerning the Fort Totten resuscitator and requested an examination of the Army's procurement of this item. Other requests for information on this procurement were received about the same time from several members of the Congress.

Enclosed are two copies of our report on the procurement of the Fort Totten resuscitator by the Department of Defense. We have not requested written comments from the Department of Defense on this report. The report is also being sent to the other members of the Congress and the medical professionals, who inquired about this matter, and to the Secretary of Defense.

We do not feel qualified to comment on the technical aspects of this matter. However, in view of the reservations expressed in the comments and opinions of several medical professionals (see appendixes I-IX of the report) we believe that the Army should not buy more than the 422 resuscitators ordered in January 1971 until more assurance is obtained as to the usefulness of the equipment.

We trust this information is responsive to your needs.

Sincerely yours,

Comptroller General  
of the United States

Enclosures - 2

The Honorable Edward W. Brooke  
United States Senate



COMPTROLLER GENERAL OF THE UNITED STATES  
WASHINGTON, D.C. 20548

B-165631

JUN 29 1972

CA Dear Senator Kennedy:

Reference is made to your June 1971 letter in which you refer to a letter from Dr. W. H. Fleming which questions the procurement of the Fort Totten resuscitator by the Department of Defense. Other requests for information on this procurement were received about the same time from several members of the Congress.

Enclosed are two copies of our report on the procurement of the Fort Totten resuscitator by the Department of Defense and the original correspondence which you furnished. We have not requested written comments from the Department of Defense on this report. The report is also being sent to the other members of the Congress and the medical professionals, who inquired about this matter, and to the Secretary of Defense.

We trust this information is responsive to your needs.

Sincerely yours,

Comptroller General  
of the United States

Enclosures - 2

The Honorable Edward M. Kennedy  
United States Senate

SUMMARY OF GENERAL ACCOUNTING OFFICE REVIEW  
OF PROCUREMENT OF FORT TOTTEN RESUSCITATORS

BY DEPARTMENT OF DEFENSE

BACKGROUND

The Fort Totten resuscitator (field resuscitator, Federal stock number 6515-926-9157) is a mechanical unit developed by the U.S. Army Medical Equipment Research and Development Laboratory at Fort Totten, New York. It was designed for treatment of chemical warfare casualties because (1) such casualties cannot be treated effectively by drugs alone due to restriction of the lungs and (2) no effective commercial resuscitator capable of providing sufficient pressure for lung ventilation was available. Clinical testing of the resuscitator was performed from 1961 to 1963 by nine military and civilian hospitals using prototype units fabricated by the Laboratory. Reports on the results of clinical testing generally indicated that the item was satisfactory for its intended purpose. The tests were not conducted on casualties under actual field conditions.

A service test, defined by the Laboratory as "a test conducted under simulated or actual field conditions where the objective is to determine to what degree the item performs the intended mission," was performed in 1966 by the U.S. Army Medical Service Test and Evaluation Activity, Brooke Army Medical Center, Fort Sam Houston, Texas. This test was conducted using three prototype units fabricated by the Laboratory. The report of this test stated that, if certain modifications were made, the item would be suitable for lung ventilation of chemical warfare casualties and for general medical resuscitation under field conditions. It stated also that tests had been made under actual or simulated conditions employing medical personnel, actual and simulated patients, animals (goats), and training devices.

Engineering and maintenance tests to determine structural soundness and ease of operation were made in 1966 by Army activities. Reports on these tests, in which four prototype units fabricated by the Laboratory had been used, stated that the resuscitator was well designed and could be easily cleaned and maintained.

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On August 26, 1968, the Defense Personnel Support Center, Defense Supply Agency, requested price quotations for 1,500 production test units of the Fort Totten resuscitator, with a view to purchasing up to 5,000 production units if the procurement showed that the item could be produced economically. By letter of October 10, 1968, to the Support Center, the J. H. Emerson Company protested the procurement on the basis that adequate studies had not been made to determine the effectiveness of the item. As a result of this protest, the military services decided that the item should be reevaluated by the Office of the Surgeon General, Department of the Army, and in December 1968, the Support Center canceled the procurement.

The military services determined, upon reevaluation, that the item should be procured but that the quantity should be reduced to 422 production units. On January 28, 1970, the Support Center requested price quotations on the reduced quantity. By letter of February 23, 1970, to the Support Center, the J. H. Emerson Company again protested the procurement of this resuscitator. The principal element of the protest was that the item had not been sufficiently tested to justify the proposed use of the resuscitator when human life might be at stake.

The Comptroller General decided (B-165631, June 25, 1970) to deny the J. H. Emerson Company protest on the basis that (1) the acceptability of the resuscitator had been determined on the basis of test data and reports of record submitted by activities which performed the tests and (2) the consistent position of the General Accounting Office was that, in disagreements of that sort, determinations of the needs of the Government and the drafting of specifications to secure those needs were the responsibilities of the agencies involved and that such specifications may not be negated by manufacturers or prospective suppliers. That decision was reaffirmed on November 24, 1970.

In January 1970 requests for quotations for 422 of the resuscitators were sent to 37 small business firms--the procurement was set aside for small business--and eight proposals were submitted. Contract DSA 120-71-C-2326 in the amount of \$268,470.56 for 422 units was awarded to Globe Safety Products, Inc., by the Support Center effective

January 28, 1971. Globe Safety Products, Inc., was the second lowest bidder; the lowest bidder planned to subcontract 90 percent of the work to a large business firm and therefore the second lowest bidder received the award.

On March 1, 1971, the J. H. Emerson Company requested the Comptroller General to reopen its procurement protest on the basis that (1) adequate testing had not been done to ensure the safety and effectiveness of the resuscitator under intended conditions of use and (2) the information upon which the Comptroller General had based his decision contained numerous misstatements. Other letters from the company, and from medical professionals protesting the procurement of the Fort Totten resuscitator, were sent to several members of the Congress, the Surgeons General of the military departments, and the Comptroller General.

Three sample resuscitators manufactured by the contractor were conditionally approved by the Support Center on January 13, 1972. As of March 17, 1972, four requests from Globe Safety Products, Inc., for waivers to the contract specifications were being reviewed by the Defense Medical Materiel Board. Final negotiations cannot take place until all requests for waivers to the contract specifications have been acted upon by the Board.

A Support Center official told us the contract price was expected to change because the specifications were being modified to include a motor-driven aspirator. He also stated that delivery of the resuscitator had been delayed pending the final negotiations.



RELIABILITY OF DATA FURNISHED  
BY DEFENSE SUPPLY AGENCY

The J.H. Emerson Company, in its March 1, 1971, letter requesting that its procurement protest be reopened, stated that the data furnished by the Defense Supply Agency, on which the Comptroller General had based his decision to reaffirm the denial of the protest, contained "edited" summaries of clinical test reports which were grossly untrustworthy.

Our comparison of these summaries with the completed reports prepared by the testing activities showed that generally the summaries contained comments favorable to acceptance of the resuscitator and omitted or minimized unfavorable comments. All the reports concluded that the resuscitator was adequate to resuscitate chemical warfare casualties and that nonmedical personnel could be trained to use the item effectively.

ADEQUACY OF TESTING

In its March 1, 1971, request that its procurement protest be reopened, the J.H. Emerson Company contended that all the clinical tests had been made on hospital patients, most of whom had been intubated (tubes had been inserted into their tracheas) by trained medical men; no tests had been made on casualties rescued in the field by non-medical men in which masks, rather than tubes, had been used and in which the resuscitator had been operated electrically.

The Chief Surgical Consultant, Office of Surgeon General, Department of the Army, agreed that there had been no reports of use of the resuscitator in the field on actual casualties, but he stated that such use was not necessary to prove the safety and effectiveness of the item because the same medical results could be achieved whether the patient was in the operating room of a hospital or in an ambulance or a helicopter. Also a report of a service test showed that the unit had been operated satisfactorily (1) on a simulated patient in a chemically contaminated area while operating on a 24-volt direct-current battery and (2) in an M-43 field ambulance moving over primary and secondary roads.

Further, in December 1970 the Anesthesiology Consultant to the Army Surgeon General and the Chief of Anesthesia and Operative Service, Walter Reed General Hospital, retested the resuscitator. In this retesting the resuscitator was used on anesthetized patients in operating rooms, on post-operative patients undergoing intensive respiratory care, and on lung models. It was concluded that the item was mechanically adequate and was acceptable for short-term use for aircraft or field-ambulance evacuation of casualties having respiratory insufficiency but that the item should be limited to that use. It was concluded also that experience with the item should be carefully documented so that (1) any needed modifications could be effectively made and (2) optimum training needs in the operation of the unit could be established.

In August 1971 we furnished the eight medical professionals, who had protested the procurement, and the American Society of Anesthesiologists with copies of test data and evaluation reports on these tests and requested them to give us their views as to whether, in the light of these tests, the resuscitator likely would be successful in field use. These medical professionals were almost exclusively of the opinion that the item still had not been sufficiently tested to ensure that it would operate safely and effectively. (See apps. I to VIII.)

The chairman, Committee on Mechanical Equipment, American Society of Anesthesiologists, stated that (1) the item obviously would deliver the volume of air within an acceptable range as required by the military specification and would be no more dangerous than any other nonmanual lung inflator, (2) further limited testing would not answer the questions of the need for, and usefulness of, the item, (3) there was no comparable mechanical device available on the commercial market, and (4) the procurement and use of several hundred units seemed well advised so that the exact need for the item could be identified and so that the bugs which are inherent in any new equipment could be eliminated. (See app. IX.)

The chairman suggested that the resuscitator be used only for emergencies by trained personnel and that a warning to that effect be placed on the instrument case and in the

operator's manual. We were advised that these observations had been based on a review of test reports, a view of the resuscitator in operation on test lungs, and a discussion with the Anesthesiology Consultant to the Army Surgeon General as to the characteristics and proposed use of the resuscitator.

Copies of replies from the medical professionals that expressed their views on the additional testing by the Army in December 1970 were furnished to the Surgeon General, Department of the Army, for review and comment. By letter of September 16, 1971, the Surgeon General advised us that, in the opinion of the Army Medical Department, the resuscitator was suitable and safe for the ventilation of gas casualties under field conditions. The Surgeon General advised us also by letter of December 16, 1971, that a warning would be placed on the resuscitator and in the operator's manual that the resuscitator was to be used for emergencies only. (See app. X.)

### Conclusion

We feel that we are not qualified to comment on the technical aspects of this matter. In view of the reservations expressed by the several medical professionals, however, including the chairman of the American Society of Anesthesiologists Committee on Mechanical Equipment (see apps. I to IX), we believe that the Army should not buy more than the 422 resuscitators ordered in January 1971 until more assurance is obtained as to the usefulness of the equipment. Our decision denying the March 1, 1971, bid protest by the J. H. Emerson Company is attached. (See app. XI.)

WILLIAM H. FLEMING, M.D.  
2827 WENDLAND DRIVE, N.E.  
ATLANTA, GEORGIA 30345

30 August 1971

Mr. R. G. Rothwell  
Associate Director  
United States General Accounting Office  
Washington, D. C. 20548

Dear Mr. Rothwell:

Thank you very much for your detailed reply of 12 August 71 to my letter concerning the Fort Totten Respirator. The data you provided does modify my views somewhat; however I still have serious reservations about the unit.

First, in answer to your specific questions:

1. The need at the 24th Evacuation Hospital where I was stationed was for a general-purpose ventilator for long-term use. I realize that the proponents of the Fort Totten unit admit it will not do this job. But the need they hypothesized never existed in my Vietnam experience. Anyway, our unit could be powered only by compressed gas, so couldn't have been used except in the hospital.

2. We dealt with all types of casualties. My detailed study of 128 patients included all types of injuries. Forty-seven had head injuries, 14 had flail chests, and 67 had arterial hypoxemia from other wounds. We had very few burns, and no recognized cases of nerve gas injury. We did, however, have several narcotic overdoses, whose problems are quite similar.

3. The volume and pressure characteristics of the Fort Totten seemed to be as advertised. But that has never been in question.

4. The major drawbacks were what made the unit useless for long-term use on any patient; and useless at any time for others.

(a) The unit has only one rate. Unless the patient is paralyzed or unconscious, this is not adequate.

(b) There is no way to add oxygen. Those who need a respirator nearly always need added oxygen also.

(c) There is no way to humidify the inspired gasses. This leads to rapid drying, and limits to unit to very brief use.

(d) The unit is useful only with the patient intubated. At present only MD's and nurse anesthetists are trained to do this. The Army has never considered this training feasible for corpsmen; and until they do, they can't use this device. To try to use it with a facemask, would simply inflate the stomach, and increase the likelihood of vomiting -- with probably fatal results. This is true of virtually any volume respirator.

## APPENDIX I

(e) There is no "assist" capability, hence patients will always require another type respirator before they can get off respiratory support.

(f) All the testing done has used patients already intubated. This means that the unit has never even been tried for the purposes for which it was designed, and is ostensibly needed.

5. The unit we had could be operated only from compressed gas. The electrical operation would add versatility IF it were otherwise useful. The power aspirator we did not have; but this could only be an asset.

Now, some specific comments on the supporting data you enclosed.

With respect to the work at Brooke, let me first say that I have an enormous respect for Colonel Mendenhall as an anesthesiologist, as a teacher, and as a researcher. While he apparently was not able to devote much time to evaluation of the Fort Totten unit, his report of 16 December 70 could hardly be considered an endorsement of the unit.

Comments on each paragraph of his report:

1. This is largely descriptive.

2. True there is nothing else like it. Colonel Mendenhall places the very large IF "there is a need for this type of instrument in the field medical units at this time". I would contend that there is NOT such a need. Patients did not die in helicopters for lack of ventilation. The crew chiefs on those dust-off flights are too good to let that happen. They had some AMBU or other similar units, and they knew how to use them. And they did so. There was no need for a fancier device. It would have been nice if EVERY dust-off chopper had at least an AMBU though. There simply wasn't a need at that level. I moved patients from Long Binh to Tan Son Nhut, as did many other physicians. All we ever needed for the short hop was an AMBU. I believe that the figures at the 24th Evacuation are representative, and that if you ask the surgical consultant to USARV, he will confirm this lack of need.

3. I have no doubt that for short-term use in paralyzed and intubated patients this machine will deliver the gas to the lungs. Again, this is not in question.

4. The power aspirator I agree, without seeing it, is probably an asset.

5. Colonel Mendenhall notes a need for two modifications before the device would be potentially useful in patient care. Apparently we all picked up these defects, of rate control and oxygen supplementation.

6. The problem of training is again raised. And this doesn't even touch on the question of who will insert the endotracheal tubes.

7. He notes the paucity of his experience with this unit. One and a half days and 3 patients is hardly comparable to my 9 months, 128 patients, and over 1200 patient days of respirator use studied in a combat area.

Next, with regard to Colonel Ritter's evaluation. I haven't had the opportunity to meet Colonel Ritter, but have no reason to question his results. They are perfectly consistent with my own observations. He did not even have the benefit of a brief clinical trial. His paragraphs 1 and 2, I readily accept. He also comments on the inadequacy of the fixed rate and paragraph 2 is almost wholly a notation of defects. Paragraph 3 likewise notes the lack of oxygen addition capability. Paragraph 4 comments on a defect which I had not encountered, but which is a common failing of respiratory assist devices. So other than the fact that the pump works, this man has nothing good to say about the unit, and notes several defects. And of course, he never comments on the need for intubation of the patient, or whether such a device is needed.

I see no need to argue minor points on this device. In the big picture, I just can't see a place for it. Nowhere have I personally seen any need for such a device; and part of my mission in Vietnam was to make note of any such need, and to document the need. Not only did I not note such a need, but none of the people around me mentioned such a need; nor was any such need mentioned to any of the other officers of WRAIR-V. Surgeon General Jennings, in a letter to Senator Brooke dated 15 April 1971, mentions that the respirator "has received extensive testing both in the field and in hospitals..." I therefore recognize the possibility that General Jennings may have other data, which I am not aware of. If so, perhaps he will make it available to you. But the data I know of cannot be called extensive, and little if any has been in the field. Certainly the data from ten years ago doesn't warrant this description; and the two recent reports are surprisingly limited in scope, and serve to re-emphasize the defects of the device.

Next is the problem of where such a highly specialized device, useful if at all only for short hops en route to the hospital, and mainly for gas attacks, would be kept. Since it isn't routinely useful or used, would it ever be anywhere that it might be available if a gas attack occurred? This I seriously doubt.

Then, in keeping with Colonel Mendenhall's question of training, who is going to make the decision to train medics to intubate the trachea? Can it be done? So far the answer is no.

So in summary, I feel that the data provided fails to answer my original objections:

1. The device has a fixed rate. This defect was noted by all evaluators.
2. It lacks provision for adding oxygen or humidification. Again, confirmed by all evaluators.
3. It is unsuited for general use. This all evaluators agree on, and in fact this is admitted by the proponents of the device.
4. No need for any such device has been demonstrated. The patients are already doing well in the area where it is proposed to use this device.


APPENDIX I

5. There has been no provision for training of personnel in tracheal intubation. I've never been sure whether this is feasible -- but if so, it would be just as useful with AMBU bags, so why not show that it can be done first.

6. Realistically, in the early care of casualties with a need for respiratory support, a 1:1 ratio of medics to patients is already the routine. So as a practical matter, present equipment, in ample quantity, is already available.

In toto, then, I still believe that procurement of the Fort Totten respirator would be a waste of the taxpayers money.

Yours sincerely,



WILLIAM H. FLEMING, M. D.  
Chief, Thoracic Surgery

WHF:sa

THE UNIVERSITY OF CHICAGO  
DEPARTMENT OF ANESTHESIOLOGY  
950 EAST 59TH STREET  
CHICAGO • ILLINOIS 60637

September 16, 1971

R. G. Rothwell  
Associate Director  
United States General Accounting Office  
Washington, D.C. 20548

Dear Mr. Rothwell:

In reply to your letter of August 12, 1971 requesting my views on the recent retesting of the Fort Totten Resuscitator, I have reviewed the reports of Colonel Mendenhall and Colonel Ritter.

Unfortunately, these scant results confirm my objections and indicate that, while the results are not applicable to field conditions, the Fort Totten Resuscitator is not suitable for general medical use or for use in critically ill anesthetized patients. Colonel Mendenhall's report shows results in only three patients, all of whom sustained a degree of hyperventilation, both excessive and progressive as indicated by the decreasing CO<sub>2</sub> values. Had these patients been as hypovolemic as actual casualties, the resuscitator could have compromised the circulation. It must be emphasized that there are no means on the Fort Totten Resuscitator to reduce either rate or volume delivered as may be practiced with manual methods of self-refilling bag and mask ventilation under such circumstances. This limitation cannot be ignored in selecting a safe means to ventilate casualties.

Further, all patients apparently had tracheal intubation, which thereby prevented the complications to fixed-volume ventilation by mask. These complications are: (1) hypoventilation due to mask leak, and (2) gastric inflation due to partial airway obstruction including laryngospasm. In most instances, in the field the Fort Totten Resuscitator would be used with a mask. If the casualties to be evacuated by aircraft or military vehicles would routinely have a tracheal tube in place...and further, if there were means incorporated in the resuscitator to decrease the tidal volume when the casualty's pulse and blood pressure became compromised, then I could accept a limited usefulness of the Fort Totten Resuscitator for airborne evacuation. However, lacking these ideal conditions I must agree with Drs. Safar, Dripps, Slocum, Jenicek, Benson, and many other authorities that the simpler, less complicated manual bag and mask methods are preferable, safer and far better suited for the evacuation of casualties.

On the other hand, if the management of casualties can include tracheal intubation ROUTINELY, then a mechanical resuscitator is obviously useful and advantageous for airborne evacuation of casualties. However, such a resuscitator should have available several rates and volumes for accommodating the full range of patients and their condition.



Mr. Rothwell  
September 16, 1971  
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The recent studies are not convincing. I cannot reverse my judgment and conclusions based on considerably more patients in 1961. We found the use of the Fort Totten Resuscitator, employing realistically a mask:

- 1.) produced excessive ventilation in small adult patients,
- 2.) produced gastric inflation in patients with low pulmonary compliance or high airway resistance,
- 3.) was poorly tolerated by semi-conscious patients as a result of the high inflation flow rate and
- 4.) was unsuitable for general use in anesthesia because of the fixed tidal volume.

Airway pressures as high as 48 cm. of H<sub>2</sub>O were observed in non-intubated semi-conscious patients, some of whom developed partial laryngospasm in response to this high-flow inflation rate.

In summary, I cannot see how the testing on three intubated patients shows the Fort Totten Resuscitator to be an acceptable device.

Sincerely,



James O. Elam, M.D.  
Professor of Anesthesiology  
Professor of Obstetrics and Gynecology

JOE:jg



**Virginia Commonwealth University**

Mr. R. G. Rothwell  
 Associate Director  
 U. S. General Accounting Office  
 Washington, D. C. 20548

Dear Mr. Rothwell:

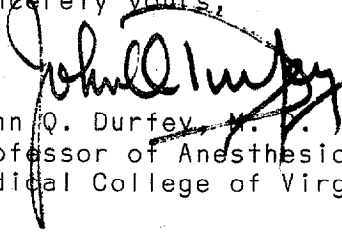
I have received your letter of 12 August, 1971, with the enclosed materials. It is obvious that the best appraisal the Fort Totten resuscitator could get was less than luke-warm, and that there are some serious defects in the unit.

It is also obvious that the unit did not receive an adequate retesting. The commentary to the effect that one could not reproduce field trials without considerable effort is not germane since the equivalent exists every day, in every state, in every city, and in every major hospital that handles accident victims. The additional commentary regarding the need for oxygen enrichment is a very strong adverse criticism; so is that regarding the development of continuous positive pressure under certain conditions.

The combination of hyperventilation, as shown even in the inadequate number of patients used in the study, plus continuous positive pressure ventilation, plus the lack of oxygen, will neatly kill very quickly any patients who have had severe blood loss.

In summary, then, I think the retesting was inadequate, the resuscitator is inadequate, and the evaluation was inadequate. I would suggest further that this equipment be tested outside the Army by University Hospital personnel who are accustomed to evaluating, in civilian emergency patients and under comparable conditions, such resuscitative equipment.

Sincerely yours,

  
 John Q. Durfey  
 Professor of Anesthesiology  
 Medical College of Virginia

JQD/bh

August 20, 1971

APPENDIX IV

**MEYER SAKLAD, M. D.**  
**DEPARTMENT OF ANESTHESIOLOGY**  
**RHODE ISLAND HOSPITAL**  
**PROVIDENCE, RHODE ISLAND 02902**

August 18, 1971

Mr. R. G. Rothwell  
Associate Director  
United States General Accounting Office  
Washington, D. C. 20548

Dear Mr. Rothwell:

Thank you very much for your letter of August 12, 1971 with the enclosures.

In your letter you wish me to send you my views on: 1) whether the testing recently performed changes my opinion on a certain resuscitator, and 2) my opinion as to whether the apparatus can reasonably be expected to be effective under "actual conditions."

You also wish my opinion as to whether the apparatus is "likely to be successful for field use for paramedical personnel."

I shall try to answer these questions in the above sequence. First, in regard to whether there has been any change in my opinion of this ventilator. I had at no time expressed an opinion as to the worth of this resuscitator. I entered the picture because I had been informed there was considerable controversy, and I suggested only that the testing programs be reviewed to determine whether the purchase of this apparatus was indicated.

In regard to my opinion as to whether the "additional testing" would be "reasonable grounds for believing that the resuscitator would prove successful for intended use under actual conditions," an answer to this would depend on, of course, what are the actual conditions. I was under the opinion that these ventilators were to resuscitate patients who had suffered from nerve gas poisoning. If this is so, then actual conditions would impose severe challenges to resuscitators. Later, in your letter, you say that the unit is to be "only used for providing short-term resuscitation until . . . more sophisticated resuscitator equipment is available." If the short-term resuscitation is indeed for nerve gas casualties and if such "short-term" is of more than a minute or two, then it would seem to me that the equipment should be considered more than a simple tool.

Mr. R. G. Rothwell

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August 18, 1971

In regard to the use of a particular ventilator by paramedical personnel, it is my view that if ventilators are to be used at all in emergency conditions, it will have to be used by paramedical personnel and paramedical personnel should and can be trained to this end.

The following is my review of the evaluation procedures enclosed in your letter from Colonel M. K. Mendenhall dated December 16, 1970 (Enclosure 1), from Colonel Richard Ritter (Enclosure 2) dated December 30, 1970, and again from Dr. Mendenhall (Enclosures 3, 4, 5) reporting on studies made during the period of July 26-30, also included (Enclosure 6) is report by Doctors Spitzer and Allen.

#### ENCLOSURE 1.

"Not a sophisticated instrument, not designed for long-term respiratory support in its present form." The apparatus is very light, simple, and rugged. The resuscitator was used on anesthetized patients and on post-operative patients in the intensive care unit. Clinical trial demonstrated that the "instrument was clinically adequate" and that the aspirator is superior to a hand or foot manual type. It is suggested that additional cycling rate be made available to the rate approximately of 16 and oxygen enrichment should also be made available.

Colonel Mendenhall states that, "experience with the instrument should be very carefully documented so that any further modifications may be effectively made."

#### ENCLOSURE 2.

This study was made on a laboratory basis using compliance and resistance units. Two compliances, 0.05 and 0.02 liters per centimeter of water; and two resistances, 5 and 50 centimeters of water per liter per second were used.

It is noted that "no studies were done to measure the effectiveness of this resuscitator when used under conditions where resistance to flow exceeds 50 centimeters of water per liter per second." Under the conditions of the experiment of "fair compliance and large resistance ...expiratory pressure did not return completely to atmospheric and under these conditions could lead to sufficient increases in positive end-expiratory pressure to compromise the cardio-respiratory system." The author further states that, "this phenomena is not peculiar to this

particular unit." The observation is made that to prevent this, "end-expiratory pressure" that adjustments to the inspiratory and expiratory ratios should be made. The author states that "this . . . limits the usefulness of this resuscitator. . . . a field resuscitator." The author recommends that means for oxygen enrichment be incorporated.

It is pointed out that during trial, "an improperly seated valve allowed most of the output of the resuscitator to be directed to the expiratory port with little measurable flow to the patient inspiratory port."

### ENCLOSURE 3.

This enclosure presents three case reports and a summary of data obtained by the pulmonary research laboratory, Brooke Army Medical Center performed by Captain Spitzer and Major Allen.

Briefly, in regard to the three case reports - none of them have any pulmonary complications. At no time were there any serious impedance to airflow. These three offered a very little challenge to a ventilator. One could conclude from these three case reports that the ventilator has the capacity to over-ventilate patients who had no impedances to airflow.

The report by Doctors Spitzer and Allen in regard to studies of the ventilator reveal changes in phenomena in regard to the introduction of impedances into the line.

The following summarizes the conclusions from the submitted data. From enclosures 1, 2, 3, 4, and 5 - one may conclude the following:  
The apparatus

1. is Not sophisticated .
2. is not designed for long-term respiratory support in its present form.
3. is clinically adequate for patients with normal airflow impedances.
4. has a single cycling rate of 16.
5. lacks the facility for oxygen enrichment.
6. tried out against lung models with two compliances, 0.05 and 0.02 liters/centimeter, and two resistances, 5 and 50 centimeters of water per liter per second.
7. functioned badly during trial because of an improperly seated valve.

Mr. R. G. Rothwell

-4-

August 18, 1971

From enclosure 6 one learns that tidal volumes were maintained in the face of increasing impedances up to 91.53 centimeters of water per liter per second and that with an impedance of 166.75 liters per second the tidal volume dropped to 156 milliliters.

From the above data, it is quite difficult for me to determine the effectiveness of this ventilator. First, it would be important for me to have some idea as to what was expected of the ventilators.

An important consideration of ventilator function is how it functions against impedances. The sort of information required to determine this comes from such work as appears in enclosures 2 and 6. From the summaries of these works there isn't quite enough information to come to a conclusion. If I could have the following answers, it would aid me considerably in coming to an opinion.

From enclosure 2:

1. The experimental setup.
2. The experimental procedure.
3. Tidal and minute volume deliveries under experimental conditions.
4. Flow patterns engendered.
5. What adjustments were made on the ventilator with changes in compliance and resistance.

From enclosure 6 I would require the above information as well as the size of the compliance chamber employed and information as to the mechanism behind the increased rate when the resistance was changed from 91 to 166 centimeters of water per liter per second.

Very truly,

  
Meyer Saklad, M.D.

MS/cm

# THE NORWALK HOSPITAL

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NORWALK, CONNECTICUT • 06856 • TEL. 203-838-3611

May 8, 1972

R.G. Rothwell, Associate Director  
Defense Division  
United States General Accounting Office  
Washington, D.C. 20548

Dear Mr. Rothwell:

Thank you for keeping me informed as to the latest evaluations that are being performed on the Fort Totten Resuscitator. While it is difficult to simulate in an Engineering Laboratory a casualty situation, it is quite possible to do this in any hospital's emergency room. Further, a proper evaluation would require several days and perhaps months of testing in order to properly evaluate a device which could probably effect the lives of many of our military personnel.

In reviewing Colonel Mendenhall's and LTC. Ritter's report I cannot justify their foregone conclusions for the following reasons:

1. The Respirator delivers a fixed tidal volume at a fixed rate. Colonel Mendenhall in no.7 of his evaluation states that "unimpeded delivery of the instrument was 0.913 liters at a peak rate of 63 liters per minute" this indicates that the instrument has a tidal volume of 0.913 liters. An individual's normal tidal volume is usually between 0.4 and 0.6 liters. If the instrument has a peak rate of 63 liters per minute and a fixed frequency of 16 breaths per minute, then the tidal volume would approximate 4.0 liters. This is larger than predicted values for vital capacity in some cases.
2. Whether a device is used for short term or long term resuscitation, please remember that each respiratory cycle lasts for approximately 4 seconds. Ventricular tachycardia often results when a normal individual hyperventilates for fifteen minutes.
3. Colonel Mendenhall also states that the instrument has no capability for oxygen enrichment. It is standard procedure to use oxygen for resuscitative measures whether the casualty be in an open field or on one of the nation's highways. In addition, the length of tubing used or the so called "dead space

*"Your Community Medical Center" serving*

NORWALK	WESTPORT	WILTON	WESTON	NEW CANAAN	DARIEN
RIDGEFIELD	GREENS FARMS	REDDING	SOUTHPORT	GEORGETOWN	

R.G. Rothwell (continued)  
 May 8, 1972

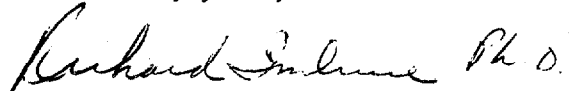
of the system" changes the actual delivered volume.

4. Reference is made to LTC. Ritter's report utilizing a Lung Model to evaluate respirator performance. It is interesting to note that LTC. Ritter's report states that the "effectiveness of the resuscitator when used under conditions where resistance to flow exceeds 50 cm H<sub>2</sub>O/L/sec." were not evaluated. In many instances, pressures as high as 120 cm H<sub>2</sub>O/L/sec. may be needed to overcome resistive and compliant changes that occur with chest injuries. He also states that the expiratory pressure does not return to atmospheric on exhalation. When this occurs, it is possible to over inflate the lungs to such an extent that a pneumothorax could result. This also can impede the return of venous blood to the heart. In this case I must disagree with LTC. Ritter's statement that most respirators have this problem. Our department does not accept a respirator which has uncontrolled positive pressure at end expiration. LTC. Ritter also expressed a desire for oxygen enrichment for this respirator. This point involves proper functioning of the non-rebreathing valve assembly. This is very critical since a poorly functioning valve could direct all of the resuscitators output to the exhalation port of its tidal volume, giving very little tidal volume to the patient.

Finally, enclosures 3, 4 and 5 of Colonel Mendenhall's report in effect state that the Fort Totten Resuscitator hyperventilates all three patients. Hyperventilation is evidenced by the PCO<sub>2</sub> changing from: 30 to 20 mm Hg; 24 to 16 mm Hg; and from 38 to 18 mm Hg; at the same time the Ph changed from: 7.50 to 7.67; 7.55 to 7.64; and 7.39 to 7.615 respectively. It is also interesting to note that in all cases even though the FI<sub>02</sub> remained constant the arterial P<sub>02</sub> dropped considerably. This could indicate an increased work of breathing and a change in the ventilation-perfusion ratio of the lung. These changes often occur when respiratory alkalosis is present.

In conclusion, the Fort Totten Resuscitator is inadequate for its intended purpose until the specified improvements are made.

Sincerely yours,



Richard Imbruce, Ph.D.,  
 Pulmonary Physiologist,  
 Technical Director,  
 Respiratory Technology Department

RI:ac



*UNIVERSITY of PENNSYLVANIA*

PHILADELPHIA 19104

*Department of Anesthesia*  
3400 Spruce Street

August 19, 1971

Mr. R. G. Rothwell  
Associate Director  
United States General  
Accounting Office  
Defense Division  
Washington, D. C. 20548

Dear Mr. Rothwell:

Thank you for your recent letter about the Fort Totten resuscitator. Herewith my comments.

The new evaluation by the Army offers little new information. This is understandable since Colonel Mendenhall and Colonel Ritter looked at the unit for only a day and a half.

Almost any resuscitator will move air in and out of a person if its use is properly taught. Those of us who have worried about manufacturing the Fort Totten unit believe that a better one can be constructed. As I understand it, one of the key features of the Fort Totten device is the air compressor. If this is really good, it could be combined with such simple units as the mini-vent or the East Freeman auto-vent both described in Mushin's new book on Automatic Ventilation. This is just one possibility and offered only as an example.

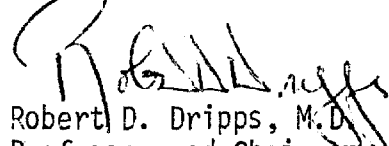
I have been led to believe that the use of manual resuscitation has proven difficult in helicopters and field ambulances for several reasons, including the possibility of multiple patients making for difficult access, patients lying on their side making a manual technique awkward, or an operator tiring after 15 to 20 minutes. These problems do suggest use of a mechanical device with the constant recognition that the airway must be maintained free and open or nothing will be of value to the wounded soldier with respiratory inadequacy.

Mr. R. G. Rothwell  
Page 2  
August 19, 1971

Assuming that the Fort Totten unit is small, assuming that proper training in its use will be offered and assuming that the Army will continue to look for improved models, I suppose you could go ahead with bids. I have minimal enthusiasm for it believing that this country can do better. I would hope the minimum number would be ordered and that they would neither be widely distributed nor relied upon to any great extent.

Perhaps in the usage they'll prove themselves to be fine units. I hope so.

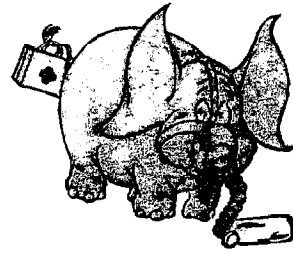
Cordially yours,

  
Robert D. Dripps, M.D.  
Professor and Chairman  
Department of Anesthesia

RDD:jaf

THE  
CHILDREN'S  
HOSPITAL  
MEDICAL  
CENTER

DEAN CROCKER, M.D., DIRECTOR  
RESPIRATORY THERAPY DEPARTMENT  
300 Longwood Avenue  
Boston, Massachusetts 02115  
Telephone: 734-6000 Area Code 617  
Cable: CHIHOSPCTR BOSTONMASS



September 1, 1971 *al Capp*<sup>er</sup>

R. G. Rothwell  
Associate Director  
Defense Division  
United States General  
Accounting Office  
Washington, D.C. 20548

Dear Sir:

Re: Fort Totten Resuscitator FSN 6515-926-9157

After reviewing the material contained in your letter of August 12, 1971, I can find no support for adopting the Fort Totten Resuscitator mentioned above. However, it puzzles me why this apparatus is still being investigated at public expense while there are currently available machines which are safer, better, and less expensive. In addition to myself I have communicated with a number of experts in the medical field who also feel that this machine is not useful, or indeed up to the current standards of therapy.

I would appreciate any further comments which you have regarding this equipment.

Yours very truly,

Dean Crocker, M.D.  
Medical Director

DC:jf1

CC: Senator Edward W. Brooke  
Senator Edward Kennedy



THE UNIVERSITY OF TEXAS MEDICAL BRANCH  
GALVESTON, TEXAS 77550

Roy D. Wilson, M.D.  
Professor of Anesthesiology

September 24, 1971

R. G. Rothwell  
Associate Director  
United States General Accounting Office  
Washington, D. C. 20548

Dear Mr. Rothwell:

I am sorry to have delayed in replying and assure you the delay is not from a lack of interest. I have in addition to consideration of the submissions you made to me in your letter of August 12 made additional inquiries from other people knowledgeable in this area with whom I have liaison. Many of the considerations of the second submission of testing are the same that were made with the original testing i.e. the senior anesthesiologist from the army used the device on anesthetized and paralyzed patients, hardly "field conditions".

In spite of the simplicity, both consultants recommended additions necessitating complications. The apparatus still requires training and specifications are suitable for resuscitation of a physiological comatose patient if such a patient existed, but is of serious question in specifications for a pathophysiological patient's resuscitation.

I sincerely believe that any anesthesiologist evaluating this instrument would agree it is useless without prior knowledge of airway management and probably less useful than exhaled air method or compressed air bags with minimal knowledge of airway management.

The enclosed reports would be interpreted by me as less than enthusiastic in spite of what might appear obscure wording. There can be no question but that such apparatus could be tested in well organized city ambulance squads on accident and natural disease resuscitation patients on a limited scale if continuation appears justified. If successfully utilized by this type of person on these relatively simple to ventilate casualties I would be more receptive than to their potential in military applications i.e. nerve gas et al.

APPENDIX VIII

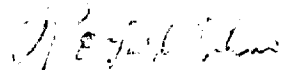
Mr. R.G. Rothwell  
Washington, D.C.

September 24, 1971  
Page 2

In short my original opinion is only refortified by the more recent reports and upon further discussions with individuals knowledgeable not only in ventilatory problems but actually experienced in Viet Nam casualty care. Mechanics are no substitute for experience and applied knowledge of anatomy and physiology.

Thank you for this opportunity at a second look. I will appreciate the continued follow-up on this item.

Yours very truly,



Roy D. Wilson, M.D.  
Professor of Anesthesiology  
The University of Texas  
Medical Branch

RDW:lp

Date: 9 November 1971

To: R. G. Rothwell, Associate Director of the Defense Division  
of the U. S. G. A. O.

From: Louis R. Orkin, M. D., Chairman, Committee on Mechanical  
Equipment, American Society of Anesthesiologists

Re: Field Resuscitator. F.S.N. 6515-926-9157

I have reviewed the information packet on the Resuscitator, Field, 6515-926-9157, sent to me through the American Society of Anesthesiologists, including technical characteristics and military specifications. I took further opportunity to view the device and see it in operation on test lungs. I discussed the characteristics of the apparatus and its programmed proposal for use with Col. Max Mendenhall. In background, I reviewed, with development personnel from Fort Totten, a prototype of this apparatus some five or more years ago.

In my opinion, no further limited testing of this instrument would answer the two major questions concerning the need for such an apparatus or the usefulness of this specific design. Obviously, it will deliver a volume of air within an acceptable range of 900 cubic centimeters, as required under specifications 3.3.2.1.5.5. on page 11 of the military specification list MIL-R-36563A., at a rate of near 18 cycles per minute, and with an inspiratory / expiratory ratio of approximately 1:2 under reasonable load conditions.

I would suspect that some of your information input has centered around a danger to the casualty patient with a fixed-volume potentially high-pressure mechanical lung inflator particularly if an endotracheal tube is not in place. I believe that this danger is inherent in any mechanical lung inflator and is more a function of the airway rather than the characteristics of the ventilator. The manually-squeezed bag is less prone to inflate the stomach only because the peak pressure is limited by the operator's skill, vigilance and determination. It would appear, moreover, that the field resuscitator would be no more dangerous than any other non-manual powered mechanical lung inflator, unless an unacceptable (from the standpoint of weight, durability, and operator training) degree of sophistication were built into the field package.

The exact extent of the need for such a resuscitator may be somewhat limited, the emergency resuscitator must be balanced against the availability of a standby human or other machine resuscitator. I concede, however, that the ultimate requirement could be estimated only by the Armed Forces Medical Services. A limited production of this instrument with placement in medical units and vehicles intimately involved with casualty

Copy to: M. T. Jenkins, E. Siker, F. Mayes, Max Mendenhall, Jack Mayers, Jack Andes.

## APPENDIX IX

Page Two

transport from the site of injury to the mainstream of definitive care would identify the exact need and would give the Armed Forces an opportunity to iron out "bugs" inherent in this or any new piece of equipment, including the most sophisticated. This would require supervision of and reporting by personnel specifically trained in use to prevent injury to the patient requiring respiratory support. For this reason, I would suggest that it be stressed that the resuscitator is to be used for emergencies only, where lack of respiration is life threatening, and that such a warning be conspicuously applied to the case of the instrument (i. e., for use in emergencies only by trained personnel). Further, this same warning should be clearly stated in the operator's manual.

Q I am in full agreement with paragraph 2 of the letter written by Col. Mendenhall, dated Dec. 16, 1970, that there is a complete paucity of comparable line production multipowered capability mechanical devices available on the commercial market at this time. The proposed limitation to short term respiratory support in evacuation vehicles outlined in paragraph 1 of that letter seems reasonable and well advised. An initial procurement of some hundreds of such resuscitators seems reasonable and well advised. However, a complete re-evaluation of the general need for such a field resuscitator and, specifically, whether a new design is needed before ordering an additional supply seems also to be wise. If the questions could be answered in actual or simulated combat operations rather than through further fruitless limited try-outs and debate, future efforts could be programmed.



DEPARTMENT OF THE ARMY  
OFFICE OF THE SURGEON GENERAL  
WASHINGTON, D.C. 20314

16 DEC 1971

DASG-DDL-T

Mr. R. G. Rothwell  
Associate Director  
Defense Division  
United States General Accounting Office  
Washington, D. C. 20548

Dear Mr. Rothwell:

This is in reply to your letter of 20 September 1971 relative to the field resuscitator (FSN 6515-926-9157) developed by the U. S. Army Medical Equipment Research and Development Laboratory.

I have delayed answering in order to have the benefit of the findings of the American Society of Anesthesiologists with respect to the tests it performed on the resuscitator. A copy of these findings was just recently received. My professional staff has reviewed the comments submitted with your letter and the report of the American Society of Anesthesiologists. They endorse the ASA report and agree that the resuscitator is suitable for emergency use on casualties in the field. The ASA recommendation with respect to placing a warning on the resuscitator and in the operator's manual, that it is to be used for emergencies only, will be followed.

Thank you for the courtesy and consideration you have shown during your investigation. If I can be of any further assistance, please feel free to call upon me.

Sincerely,

A handwritten signature in cursive script that reads "Hal B. Jennings, Jr." followed by a flourish.

HAL B. JENNINGS, Jr., M. D.  
Lieutenant General  
The Surgeon General





COMPTROLLER GENERAL OF THE UNITED STATES  
WASHINGTON, D.C. 20548

B-165631

J. H. Emerson Company  
22 Cottage Park Avenue  
Cambridge, Massachusetts 02140

Attention: Mr. John H. Emerson  
President

Gentlemen:

Reference is made to your letter of March 1, 1971, and subsequent correspondence requesting reconsideration of our decision B-165631, June 25 and November 24, 1970, which denied your protest under RFP No. DSA 120-70-R-1216, issued by the Defense Personnel Support Center, Defense Supply Agency (DSA), for the procurement of 422 Field Resuscitators, 110 volt, 60 cycle, AC, or 24 volt, DC, Stock Number 6515-926-9157.

The principal element of your protest involved the proposition that the devices had not been sufficiently tested to justify the proposed uses of the resuscitators.

In response to your allegation DSA furnished us with a comprehensive report from the Medical Equipment Research and Development Laboratory (MERDL), Department of the Army, which stated that the resuscitators had been given extensive laboratory and clinical tests at several civilian and military installations during the development of the units; that clinical tests were also made at various stages with prototypes of the device on human patients; that the basic durability and suitability of the device had been demonstrated in a 1,000 hour continuous duty test at Aberdeen Proving Grounds which was stated to simulate many years of normal use; and that the unit eliminated the need for using a proprietary resuscitator valve.

In view of such data and the well-established position of our Office to accept the technical determinations of the procuring agencies unless such decisions are shown to be arbitrary, we could not conclude

B-165631

that an adequate basis had been established which would justify our interference with DSA's proposed procurement of the resuscitators. In view thereof, DSA proceeded with the procurement and made an award under the subject RFP to Globe Safety Products, Inc., on January 28, 1971.

You now state that the procurement is designed to benefit an engineer employed by MERDL who possesses a patent on the resuscitator; that the use of your resuscitator valve does not restrict competition in resuscitator procurements; that the device as specified will not operate on tanked oxygen; and that the MERDL report, noted above, contained misstatements. You also state again that the devices have not been sufficiently tested to justify purchasing the subject requirement.

In reports dated April 5 and April 26, 1971, copies of which have been furnished to your concern, DSA has furnished this Office with responses to your allegations.

With respect to your statement that a MERDL engineer will financially benefit from the patent which he has on the resuscitator, MERDL states that the Government has been granted an irrevocable, world-wide, nonexclusive, royalty free license to the device, and that there can be no financial benefit to any individual as a result of Government procurement. We cannot dispute such position on the basis of the present record.

Concerning your statements that the Emerson resuscitator valves are not restrictive in procurement and that the specified resuscitator does not operate on tanked oxygen MERDL has replied as follows:

"Every commercial resuscitator valve marketed is restrictive in procurement and repair parts to a single source. Only if a specification is prepared on a performance basis, is it possible to obtain competitive bids. However, end items offered are different from each other in construction and repair parts. By contrast the MERDL unit employs off-the-shelf components manufactured by firms not in the business of making resuscitators. They have distributors throughout the country and publish catalogs,

B-165631

with price lists. The end item manufactured by any source would be completely interchangeable with a similar item produced by another manufacturer. In most cases, off-the-shelf components capable of being used are available from several sources. Although the Bill of Materials accompanying the detail drawings gives one source for each item, the specification provides for other sources. The many straight specification bids received during requests for quotations for the resuscitator, attests to its non-restrictive status.

\* \* \* \* \*

"The MERDL resuscitator is a gas driven device, capable of being driven equally well from the integral electric air compressor, from external manifold lines, or from external tanked gas. It was the professional desire that the basic source of power be 110 Volt 60 cycle AC or 24 Volt D.C. vehicular power. However, it was recognized that on occasions it may be desirable to have the unit operated from tanked gas (particularly in those cases where electricity is not available, or in an explosive atmosphere where an electric motor driven compressor is considered a hazard, or where the compressor noise is objectionable). Since medical units having tanked oxygen also have regulators, such as FSN 6680-935-4242, Regulator, Pressure, Medical Gas Administration, Lightweight, Oxygen with Flowmeter, and it is simple to substitute quick connect fittings, furnished with each MERDL resuscitator, for the flowmeter, it is not considered necessary to include a regulator with each resuscitator unit. Thus, as furnished, a medical unit having oxygen, would have no difficulty in using fittings supplied with the resuscitator to convert an oxygen regulator for convenient and immediate use."

From our review of the several reports submitted to this Office we perceive no basis for disagreeing with MERDL's position in these matters.

You also state that the MERDL report omitted certain unfavorable comments concerning the results of testing the unit with an oronasal mask which were submitted by Dr. James O. Elam and Dr. Elwyn S. Brown.

B-165631

From our review of the doctors' report, we agree with your assertion. However these doctors also stated in the summary section of the report that the resuscitator, when coupled to the patient by oronasal mask, produced adequate ventilation in unconscious adults provided: (1) the mask fit was snug; (2) the patient's head was hyperextended and/or his mandible was displaced forward; and (3) the patient had a normal compliance and resistance. Furthermore, by checkmarks on a questionnaire attached to the report the doctors indicated that the resuscitator was "suitable for the intended purpose of safely and effectively ventilating casualties encountered under field medical medications"; that nonmedical personnel could be trained to "effectively use this equipment as an emergency means to resuscitate the apenic individual or to maintain ventilation in the respiratory cripple"; and that the MERDL prototype cycling unit should be "type classified as standard as a piece of field resuscitation equipment either alone or as a component part of a field resuscitation outfit." In view of these representations, we cannot conclude that MERDL's failure to report all comments in the report misrepresented the conclusions of this study as indicated on the questionnaire.

With respect to the question of the adequacy of testing employed in developing the resuscitator, our Office made a review of the complaints raised by your concern and other medical professionals. A summary of the results of that review is enclosed. As indicated therein, all of the reports of the testing activities which were available at the time of the subject award concluded that the resuscitator was adequate to resuscitate chemical warfare casualties and that non-medical personnel could be trained to effectively use the item. Accordingly, we cannot conclude that the award to Globe was improper or that it should now be cancelled as you contend.

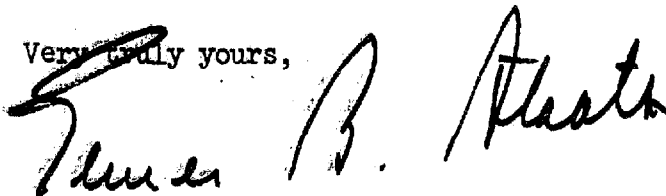
However, in view of the reservations expressed by several medical professionals, including the Chairman of the American Society of Anesthesiologists Committee on Mechanical Equipment, who evaluated current testing data on the unit at our request, we are advising the Secretary of Defense that it is our opinion that the Army should not buy additional resuscitators until more assurance is obtained as to the usefulness of the equipment.

JUN 29 1972

B-165631

For the reasons set forth above, our decision of June 25, 1970, insofar as it denied your request for this Office to cancel the subject requirement, is affirmed.

Very truly yours,

A handwritten signature in black ink, appearing to read "James B. Heath". The signature is written in a cursive style with a large initial "J" and "H".

Comptroller General  
of the United States

Enclosure