REPORT 7606

A FLASH STERILIZER USING PERACETIC ACID

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A prototype sterilizer to be used in a Military Field Environment Operating Room area whereby an accidentally contaminated instrument can be rapidly resterilized using peracetic acid and returned to use was designed and partially fabricated. The task was terminated when commercial equipment became available to perform the desired function.

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PREFACE

The U.S. Army Medical Research and Development Command (USAMRDC), Washington, D.C., initiated the Task "Flash Sterilization Using Peracetic Acid", Work Unit No. 3A162110A816.08.053, to the U.S. Army Medical Bioengineering Research and Development Laboratory (USAMBRDL), Fort Detrick, Frederick, Maryland, On 29 November 1974. The task was previously an In-House Laboratory Independent Research Project at USAMBRDL. On 1 July 1975, the task number was changed to 816.00.022. USAMRDC terminated the task 4 December 1975. This final report is in response to the work unit.

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INTRODUCTION

Background. A need existed to develop a sterilizer for use in an operating area whereby an accidentally contaminated instrument can be rapidly re-sterilized and returned to use in a Military Field Treatment Area (i.e., Combat Support Hospital).

Initially, the task started as an In-House Laboratory Independent Research Project at the U.S. Army Medical Bioengineering Research and Development Laboratory (USAMBRDL) Fort Detrick, Frederick, Maryland, on 29 November 1974. The U.S. Army Medical Research and Development Command (USAMRDC), Washington, D.C., established the Task "Flash Sterilization Using Peracetic Acid", Work Unit No. 3A162110A81[illegible].08.[illegible] at USAMBRDL, (Appendix A). USAMRDC terminated the task at USAMBRDL on 4 December 1975, (Appendix B).

Objective. The objective was to develop a means and necessary sterilization equipment to provide for effective, rapid flash sterilization of surgical instruments and devices using Peracetic Acid (CH_3COOOH).

Approach. The approach was to: (a) conduct a Literature Search to determine physical and chemical properties of Peracetic Acid; (b) develop a tentative technique for using the sterilization properties in the anticipated environment; (c) design and build a prototype sterilizer; and (d) test the equipment. The Peracetic Acid Consultant was Dr. C. R. Phillips. The Project Offices/Nursing Consultants were LTC M. Wisler and LTC D. McLeod of USAMRDC.

STATUS

Properties of Peracetic Acid. Peracetic Acid is a colorless liquid at room temperature. It is normally shipped in 40% solution with the typical composition in Table 1.

TABLE 1

COMPOSITION % BY WEIGHT

Peracetic Acid CH_3COOOH	41.3%
Hydrogen Peroxide H_2O_2	5.1%
Acetic Acid CH_3COOH	39.3%
Sulfuric Acid H_2SO_4	1.0%
Water (Free)	13.3%

It has a pungent odor, the vapors being flammable (flash point 40°C) and are lachrymatory. Microbiological tests show Peracetic Acid to be a highly efficient bactericide and fungicide even at concentrations of less than 1%. Peracetic Acid solutions 40% have a pronounced corrosive effect on human skin.

Additional chemical and physical properties are contained in the references. A partial list of compatible, noncompatible, and catalytic materials are shown in Tables 2, 3, and 4.

As an additional guide, Dr. Phillips advised that material compatible with Hypochloride would be compatible with Peracetic Acid. Mr. MacKellar (Reference 19) indicated items that catalyzed H_2O_2 or had organic double bond, would be attacked by Peracetic Acid.

Peracetic Acid literature searches of the following data banks were conducted:

a. Defense Documentation Center (DDC), report bibliography and research and development planning summary.

b. National Aeronautics and Space Administration (NASA).

c. National Technical Information Service (NTIS).

d. Science Information Exchange (SIE).

e. National Library of Medicine (MEDLARS).

Applicable references were reviewed and are listed in the Bibliography.

Proposed Design Approach. The design approach was to provide a sterilizer in the form of a sterile chamber in which peracetic acid is employed as the sterilizing agent. The system would be used as follows (Reference 8):

a. A gloved individual insert the clean instrument requiring sterilizing into the chamber.

b. The instrument is scrubbed with peracetic acid by means of a sponge, gauze pad, etc.

c. The instrument is wiped dry by means of a sterile towel, aided by a warm filtered air stream.

d. The instrument is removed, wrapped if necessary in the towel used for wiping, available for immediate use or temporary storage.

TABLE 2

COMPATIBLE MATERIAL/PERACETIC ACID

Item	Material	Reference
	Metals	
1.	AL 1060 or 5254	10
2.	SS 816 or 347 (No Storage)	10
3.	SS 304 (No Storage)	6
4.	AL 2S Purity Min	6
	Plastics	
1.	Polyethylene	10
2.	Polypropylene	10
3.	KEL-F	10
4.	Teflon	10
5.	Polystyrene	10
6.	Polyethylene Polyisobutylene	10
7.	Saran	10
8.	GE Silicone #12650	38
9.	BUNA-N	6
10.	Silicone Rubber Caulking (4% P)	6
	Other Material	
1.	Glass	10
2.	Amber Glass	10
3.	Kimax	10
4.	Pyrex	10
5.	Glazed Ceramic Tile	6
6.	Acid-Resistant Paint	6
7.	Wood (2%)	16
8.	Rubber Floor Tile	16
9.	Paper	16
10.	Cloth	16
11.	Fiber Glass	20
12.	Leather	20

TABLE 3

NONCOMPATIBLE MATERIAL/PERACETIC ACID

Item	Material	Reference
	Metals	
1.	AL (Not 1060 or 5254)	10
2.	Iron, Black and Galvanized	37
3.	Zinc	37
4.	Mercury	37
	Plastics	
1.	Various Vinyl Formulations (40%) (May be used for gasket)	10
2.	Koroseal (40% P) " " " " "	10
3.	Vinylite (40% P) " " " " "	10
4.	Tygon (40% P) " " " " "	10
5.	Natural Rubbers	10
6.	Synthetic Rubbers	10
7.	Some Silicons	10, 37
8.	Plexi Glass (40% Peracetic Acid)	38
	Other Materials	
1.	Organic Sulfur Compounds	37
2.	Organic Nitrogen Compounds	37
3.	Aromatic Nitroso Compounds	37
4.	Concrete	6
5.	Mortar	6

TABLE 4

CATALYSTS/PERACETIC ACID

Item	Material	Reference
1.	Iron	37
2.	Cobalt	37
3.	Copper	37
4.	Manganese	37
5.	Lead	37
6.	Mercury	37
7.	Dirt	37
8.	Dust	37
9.	Stainless Steel	16
10.	Galvanized Iron	16
11.	Platinum	38
12.	Charcoal	38

The peracetic acid immediately sterilizes both the instrument and the gloved hands of the operator. The device is available for immediate use, since the instrument will be essentially at room temperature and there are no residues to eliminate.

The sterilizer is to be a table top model and its chamber provided with a sloped observation window so that the operator has an unobstructed view of the chamber contents at all times. The size of the unit is such that it can be employed within the MUST operating room, where space is at a premium. Access to the chamber is by means of a full-size opening, whereby as soon as the door is opened there is generated a vertical laminar filtered air curtain so as to isolate the chamber containing the peracetic acid, from the operating room.

The interior of the chamber contains a stainless steel tray filled with a 2% solution of peracetic acid. This concentration is judged to provide adequate concentration of peracetic acid for a 24 hour operation. The peracetic acid concentration should not go below 1% during this period, a concentration adequate for sterilization. It is planned that a unit-dose package would be provided so that when contents are placed in a tray and the tray filled with water, a 2% solution will result. The preparation of peracetic sterilizing agent will be replaced each morning prior to start of surgery. The interior of the chamber will also be provided with a sponge, a supply of sterile towels, and an air outlet providing a stream of filtered warm air as an aid to drying. All traces of liquid peracetic acid must be removed from the instrument prior to removal of instrument from the chamber.

The electrical power requirements for the unit are expected to be very low and available from a standard electrical convenient outlet. Power will be required to operate an air blower which will push air through a biological filter (capable of producing sterile air) through a perforated manifold to produce the air curtain, through a vent which can either:

a. Be provided with a canister containing an absorbent material;

b. Or directly ducted outside of the operating room.

A secondary amount of filtered air will be warmed and supplied to the chamber interior to expedite wiping and drying of the sterile instrument. The design will have to consider:

a. Use of electrical devices in operating room. Either the blower unit will have to be located outside of the operating room (which will also minimize noise level of blower), above the five foot explosive gas level, or must meet Group I, Class C environmental requirements, and;

b. Minimum level of noise acceptable within an operating room.

The method described above is favored over a process involving placing of instrument in a perforated container, and dipping it into peracetic acid, and drying of instrument while still in the container. This latter method will require larger trays, accessory perforated containers, larger chamber, more air and power requirements. It will only be considered in the event that the proposed method does not meet with the approval of the professional medical evaluators.

Equipment. The current design is a cabinet, Figure 1, constructed of 1/2" Plexiglass and assembled with screw . The cabinet is 30 inches high, 28 inches wide and 18 inches deep. The front of the cabinet has two corrosion resistant steel glove ports and a hinged top access door. The glove ports are sealed using GORE-TEX(R)(1), joint sealant, 1/8" in diameter.

The intended use of the gloves is to protect the operator from peracetic acid while sterilizing the tools.

The top access door is constructed from 1/2" plexiglass and hinged at the top. The door opens out from the cabinet. A counter weight is attached to the left side in order to reduce the opening effort. The door can be opened with the hand or foot using the foot lever. The lever is attached to the counter weight by a rope going through a series of pulleys. The position of the counter weight and rope attachment point can be varied for test purposes. The door can be locked closed by a top latch. The door is sealed by Frost-King Self Stick closed cell vinyl foam tape, 1/8 inches thick, 1/4 inches wide. Non-sterile tools are introduced into and sterile tools removed from the sterilizer through the top access door.

A second door called a side access door, is installed on the right hand side of the cabinet. It is constructed from 1/2" plexiglass, can be opened or closed manually and locked in the closed position. The tray containing peracetic acid is placed into the cabinet through this door. Placement of the tray via the top door would increase the chance of spillage. The side door, in addition, aids in cleaning and maintenance of the cabinet.

Inside the cabinet is a false bottom of two removable aluminum trays. This raises the bottom of the cabinet to the same height as the lower edge of the side access door. The purpose being to prevent spillage of the peracetic acid and aid in cleaning and maintenance.

Attached to the inside back of the cabinet is a long row of corrosion resistant steel hooks. The hook assembly is attached to the cabinet wall with screws. The hooks are for placement of surgical tools when inside the cabinet.

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(1) Local distributor, W. L. Gore and Associates, Inc., Box 513, Route No. 5, Elkton, Maryland 21921

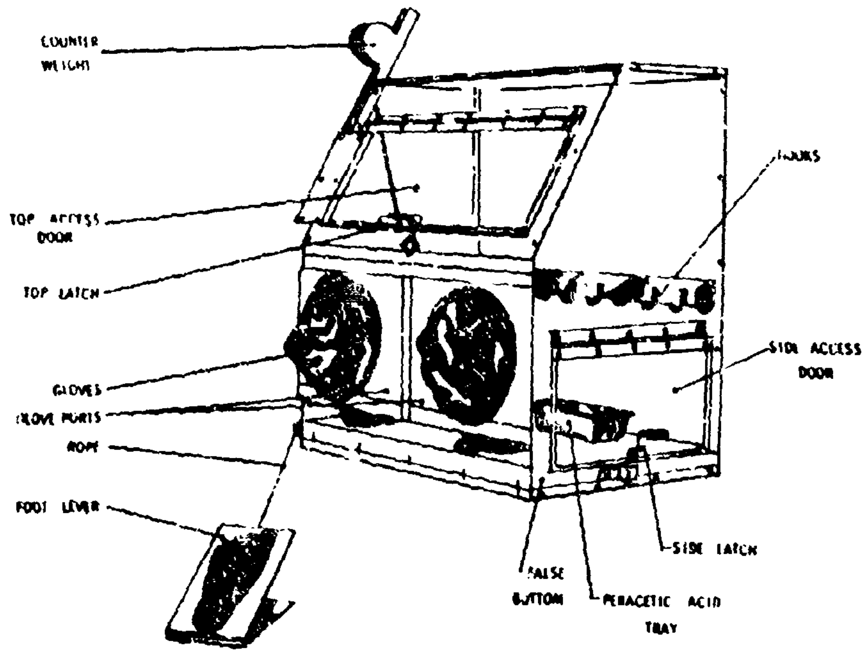

FIGURE 1. FLASH STERILIZER

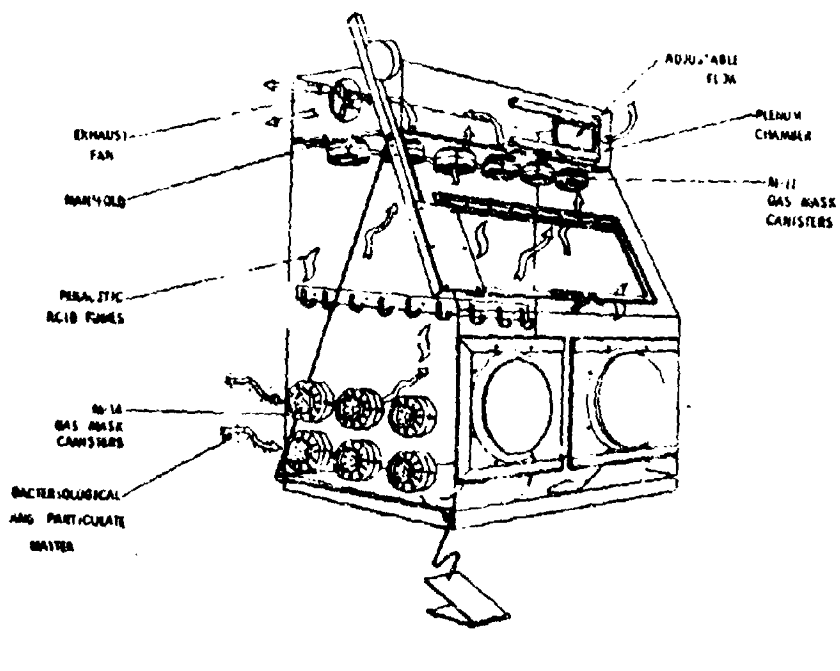

FIGURE 2. FLASH STERILIZER (PROTOTYPE)

LTC M. Wisler of USAMRDC reviewed SC6545-8-CL-D28, Department of the Army Medical Equipment Set, Clearing Station (National Stock Number 6545-00-457 6859) (Line Item Number M23471) and SC 6545-8-CL-D27 Medical Equipment Set Battalion Aid Station (National Stock No. 6545-00-457-6858) (Line Item Number M23218) for a representative list of surgical tools. The materials were ordered (Table 5) to determine materials compatability with peracetic acid, and for use in functional test of the flash sterilizer.

At this point in time, the task was terminated (Appendix B) because commercial equipment became available to perform desired function. The cabinet was not complete at this stage of development. It had been planned to incorporate an air flow system, Figure 2, to prevent acetic and peracetic acid fumes from entering the operating theater. Air was to be drawn into the bottom of the cabinet through six each M-14 Canisters, MIL-C-10082, and exhausted through six each M-11 Canisters, MIL-C-10116, at the top of the cabinet. The canisters were to be screwed onto manifolds for easy replacement. The manifolds were to be attached with screws to the plexiglass and sealed to prevent leakage.

The exhaust fan would be located in the plenum chamber at the top of the cabinet. Bacteriological and particulate matter would be removed from the intake air by the M-14 canister. The acetic and peracetic acid fumes would be removed from the exhaust air by the M-11 canister. The plenum chamber was to have an adjustable opening to control the air flow through the chamber.

An ON-OFF switch would control the exhaust fan. Two fans were available for test: (a) Muffin Fan 14 Watts 105/125 V 60 AC (2373) and; (b) An Axial Fan, AMP, 120 V, AC 120 cfm. At one point in time a Barnebey-Chaney activated charcoal canister, Air Purifier, Series C, Model CHA 8" x 25", 1 AMP, 120 cfm 120 V, 60 Hz, was considered and ordered for the air purification system. It was suggested by Dr. Phillips to use standard canisters (i.e., M-11 and M-14) in lieu of the Barnebey-Chaney equipment.

A hot air gun was considered to dry the surgical tools, but further investigation was needed to determine the most desirable type. It must be remembered that at certain concentrations, peracetic acid fumes are flammable. Also, the unit was intended to be used in an operating room which may require a type of air gun to meet explosion proof criteria.

The following additional areas of investigation have not been completed:

a. The type of trays to hold the peracetic acid.

b. The optimum number and types of gas canisters, since the entire field was not examined.

TABLE 5

SURGICAL INSTRUMENTS FOR FLASH STERILIZER

TASK NO. 816.08.053

ITEM	DATE ORDERED	DATE RECEIVED	QUANITY	UNIT COSTS	FSN	ITEM
1			4	$ .60	6515-299-8356	CATH URET RNO TIP 16 FR
2			2	6.37	8737	HOLDER SUT NOL H M 71R
3			1	12.50	6515-312-4125	BUR CRAN HUDS 14 MM
4			1	12.30	4130	BUR CRAN HUDS 20 MM
5			1	34.80	5320	BRONCH JACK 8 MM x 40 CM
6			1	32.20	6515-320-3800	CLAMP PYLORUS PAYR 81
7			4	3.52	4600	FORCEPS TOWEL BACK 51
8			1	4.82	321-0680	CABLE ASS ELECT BOEHM
9			1	2.39	327-8400	ELEVATOR PERIO SAYR
10			1	5.12	328-0700	ELEVATOR PERIO 73-4IN
11			1	19.00	331-1300	FORCEPS BONCUT CV 101
12			1	18.90	4600	RONGEUR CUR HARTM 71
13			1	45.10	4800	RONGEUR CUR STILLE
14			2	[illegible].19	333-3600	FORCEPS DRES ST 51-2I
15			2	10.50	334-1400	FORCEPS GAL DUC CV 77
16			4	4.81	4300	FORCEPS HEM CV ROCH P61
17			4	3.52	4900	FORCEPS HEM CV HAL 51
18			4	4.28	5600	FORCEPS HEM ST HAL 51
19			4	3.42	6800	FORCEPS HEM ST KEL 51
20			2	6.97	7500	FORCEPS HEM ROCH 071
21			2	10.00	335-2800	FORCEPS INT ST BAB 61
22			2	6.95	337-3900	FORCEPS PAD HLD ST 9 I
23			2	1.23	9900	FORCEPS TIS STR 5 IN
24			1	6.10	341-9800	HOLDER NEED MASS 10 I
25			1	2.20	342-2300	HOOK DURA ADSON 8 IN
26			2	.78	344-7800	HANDLE SURG KNIFE NO
27			2	1.04	356-7100	PROB BULLET
28			1	8.73	360-3490	RETRACT ABD 12 IN 1-IN
29			1	9.15	3510	RETRACT ABD 12 IN 1-IN

TABLE 5 (Continued):

ITEM	DATE ORDERED	DATE RECEIVED	QUANITY	UNIT COSTS	FSN	ITEM
30			1	$ 8.51	6515-360-3850	RETRACT ABD DBLE END
31			2	3.45	4100	RETRACT ABD 10 2x21-2
32			2	3.32	7400	RETRACT BRAIN 8 INC
33			2	4.96	9200	RETRACT GEN OPER SE 2
34			2	6.80	361-0350	RETRACT GEN OPER 4 PR
35			1	17.50	3950	RETRACT MAST TENSEN
36			2	3.12	8950	RETRACT TRACH 1 SHPPRG
37			2	6.32	8980	RETRACT TRACH 3 SHPPRG
38			2	3.79	362-0200	RETRACT VEIN CUSHIN
39			2	6.80	363-1100	SAW AMPUT 8 IN BLADE
40			2	2.94	8840	SCISS BAND ANG 7 1/4
41			2	2.47	364-0520	SCISS GEN SURG 5
42			2	3.58	365-1820	SCISS GEN SURG ST 5-1
43			1	4.41	374-6900	ELEV PERIO MATS 8 3/4
44			1	.76	375-1100	STYLET CATH MALL ST
45			1	3.05	384-5100	CANNULA BRON ESOPH 50C
46			1	8.46	518-5475	CANN TRAC MOD JACK S26
47			1	9.79	5478	CANN TRAC MOD JACK 7W
48			6	.23	660-0046	AIRWAY PLASTIC AD-CH1
49			1	7.16	914-0244	CANNULA TRACHE NYL S2
50			1	15.60	926-9193	RETRAC MAST WEIT BLP
51			2	1.40	6530-770-9220	BASIN EMESIS C-R STEE
52			6	.04	780-7000	MEDICINE GLASS 1 OZ
53			2	.32	7920-772-5935	BRUSH SURG

c. Optimum air flow necessary to prevent escape of peracetic acid fumes.

d. Procedures for use of the equipment.

e. Effectiveness of the sterilizing procedures as used with the equipment.

f. Compatability of surgical materials with peracetic acid.

Upon completion of fabrication, the unit was to be subjected to Development Test I and Operational Test I, per AR 70-1.

SUMMARY

When the task was terminated the Literature search was nearly completed and fabrication had started on the Development Test I prototype. The following areas of investigation remained to be completed:

a. Selection of a hot air gun that will dry the equipment and be compatible with the environment.

b. Surgical instrument materials compatability with peracetic acid.

c. Type of trays to hold the peracetic acid.

d. The optimum number and types of gas canisters for air filtration and purification since the entire field was not thoroughly examined.

e. Optimum air flow necessary to prevent escape of peracetic and acetic acid.

f. Procedures for use of the equipment.

g. Effectiveness of the sterilizing procedures as used with the unit.

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APPENDICES

SGRD-SDM 29 NOV 1974

SUBJECT: Request to Initiate Project in The Military Medical Materiel Program

Commander
US Army Medical Bioengineering
Research and Development Laboratory
Fort Detrick
Frederick, MD 21701

1. Reference 1st Ind, SGRD-SDM, 15 July 1974 to letter SGRD-UBB, 19 June 1974, subject: Request to Include Projects in the Military Medical Materiel Program.

2. It has been determined that the In-House Laboratory Independent Research Project, Flash Sterilization Using Peracetic Acid, terminated per referenced correspondence, should be initiated in the Military Medical Materiel Program, as part of the Field Sterilization Study.

3. Your contributing work unit number should be 3A162110A816.08.053. Work on this facet of the Field Sterilization Project should begin at your earliest convenience. Monitor at this Headquarters is LTC Marie G. Kisler, ANC, Materiel Development Division, Surgical Research Directorate.

Signed
R. E. B.

KENNETH R. DIRKS, M.D.
Brigadier General, MC
Commanding

RICHARD F. BARQUIST, M.D.
Colonel, MC
Deputy Commander, USAMRDC

DEPARTMENT OF THE ARMY
U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
WASHINGTON, D.C. 20314

REPLY TO
ATTENTION OF:

SGRD-SDM 4 December 1975

SUBJECT: Request to Terminate Project in Military Medical Materiel Program

Commander
US Army Medical Bioengineering Research
and Development Laboratory
ATTN: SGRD-UBE-G
Fort Detrick
Frederick, Maryland 21701

1. Reference conference on project priorities, 2 December 1975, with US Army Medical Bioengineering Research and Development Laboratory (USAMBRDL) personnel determined that work unit number 3A162110A816.08.022 should be terminated.

2. The state-of-the-art does not dictate that the project, Flash Sterilization Using Peracetic Acid be continued at this time.

3. Request a Final Report be prepared and distribution made in accordance with established requirement. Further request the prototype fabricated be kept at USAMBRDL for historical purposes.

FOR THE COMMANDER:

WALTER L. SCHEETZ, M.D.
Colonel, MC
Director of Surgical Research

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