EL DORADO COUNTY
HEALTH AND HUMAN SERVICES AGENCY *Emergency Medical Services*

Daniel Nielson, M.P.A.
Director

Richard Todd
EMS Agency Administrator

EMS Safety Bulletin 2012-01

DATE: October 19, 2012

TO: All Personnel

FROM: EDCEMSA

SUBJECT: Equipment Recall

Please see the attached documents for information regarding a BVM recall from Ventlab corporation.

MESSAGE CONFIRMATION:
☐ NOT REQUIRED ■ REQUIRED ■ ACKNOWLEDGEMENT BY ALL PERSONNEL REQUIRED

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Ventlab Corporation Issues Nationwide Recall of its Manual Resuscitators

Contact:
Consumer:
1-800-593-5654

FOR IMMEDIATE RELEASE - October 16, 2012 - On July 11, 2012, Ventlab Corporation initiated a nationwide recall of 14,602 of its manual resuscitators. The manual resuscitators as listed below have been found to potentially deliver little to no air/oxygen through the patient valve to the patient, which could result in life threatening health consequences that include hypoxia and hypoventilation.

End Users who have manual resuscitators at the lot numbers listed below should stop using them and immediately contact Ventlab Corporation for further instructions on the return of these products.

Recalled manual resuscitators were manufactured and distributed nationwide to distributers that sold and distributed products to hospitals, clinics and EMS units from March 2012 to July 2012.

The following models have been recalled:

Ventlab AirFlow Adult Resuscitator:

AF1040MB	Lot# 102091	880 each
AF1040MBP	Lot# 102106, 102174	60 each
AF1040MBS	Lot# 102189	60 each
AF1040MB-S5	Lot# 102105	40 each
AF1040MB-T	Lot# 101917, 102151	20 each
AF1100MB	Lot# 102227	30 each
AF1140MB	Lot# 102081, 102139	2,250 each
AF1140MB-K	Lot# 102093, 102165	60 each
AF1140MB-P5	Lot# 102145	50 each
AF1140MBP-T	Lot# 102096	290 each
AF1140MB-T	Lot# 101666	130 each

Ventlab AirFlow Infant Resuscitator:

AF3100MB-M1	Lot# 102185	360 each
AF3140MB-I	Lot# 102129	20 each
AF3140MB-K	Lot# 102130, 101592, 101729	30 each

Ventlab AirFlow Small Adult Resuscitator:

AF5140MBPWTD5	Lot# 101806, 102163	40 each
AF5140MB-T	Lot# 102075	220 each
AFD5140MB-T	Lot# 101928, 102211	580 each

Ventlab StatCheck Adult Resuscitator:

SC9001C	Lot# 101360, 101751, 101819 101948, 102090, 102164	330 each

SC9001C-C	Lot# 101100, 101441, 101780 102193	380 each

Ventlab SafeSpot Infant Resuscitator:

SS3200MB	Lot# 100130, 100251, 100381 100432, 100656, 100791 101101, 101388	320 each
SS3200MB-2	Lot# 100131	70 each
SS3200MB-I	Lot# 101238, 101370, 101480 101820, 102009	80 each
SS3200MB-MMC	Lot# 100129	270 each
SS3200MBP-2	Lot# 102057	10 each
SS3200MBP-M00	Lot# 100132, 101462, 102051	120 each
SS3200OB	Lot# 100133, 100252, 100979 101178, 101863, 101975	330 each
SS3200OB-PW	Lot# 100253, 100134	20 each

Ventlab Premium Infant Resuscitator:

VN3100MB	Lot# 102032	630 each
VN3100MB-2	Lot# 102033	270 each
VN3100MBP	Lot# 102046, 102182	20 each
VN3100MB-PW2	Lot# 102050	10 each
VN3100OB	Lot# 102150	30 each

Ventlab Premium Small Child Resuscitator:

VN4100OB	Lot# 102015	80 each

Ventlab Premium Small Adult Resuscitator:

VN5000MX	Lot# 102194	30 each

Ventlab RescueMed Infant Resuscitator:

BVM700	Lot# 101638	12 each

BreathTech SafeSpot Infant Resuscitator:

BT2200FK	Lot# 100196	276 each
BT2216	Lot# 100138	1,800 each
BT2216F	Lot# 100139	378 each
BT2216K	Lot# 100197	204 each
BT2220	Lot# 100140	258 each
BT2220F	Lot# 100141	270 each
BT2416	Lot# 100142	210 each
BT2416F	Lot# 100143	258 each

BT2416K	Lot# 100198	276 each
BT2420	Lot# 100144	222 each
BT2420F	Lot# 100145	276 each
BT2420FK	Lot# 101081	282 each

Provider Enterprises SafeSpot Infant Resuscitator:

Pro-1904	Lot# 100155, 100183, 100451 100497, 100655, 101577	450 each
Pro-1925	Lot# 101604, 101550, 101657	1,300 each

Provider Enterprises Adult Resuscitator:

Pro-5009P	Lot# 102217	10 each

Products can be identified by the part number, description and lot number on case labels, as well as a small white label on the individual packaging bag.

Ventlab Corporation voluntarily recalled the above listed products after becoming aware of a product incident where the nature of the complaint was that the resuscitators were delivering little or no air through the patient valve to the patient. Ventlab Corporation has notified the FDA of this action.

No injuries have been reported to-date.

Ventlab Corporation has notified its distributors and customers by e-mail notification followed by a direct mailing and is arranging for the return/replacement/rework of all recalled manual resuscitators listed above.

End Users with questions may contact the company via telephone at 1-800-593-5654 between the hours of 8:30 AM to 5:00 PM (EST) Monday through Friday. Consumer may also contact the company via e-mail at csr@ventlab.com.