Advisory 17-07 Rate Control "Dial-A-Drip" Devices

To: Agency Leadership

From: Jeremy T. Cushman, MD, MS, EMT-P, FACEP
Regional Medical Director

Date: September 13, 2017

As you may be aware, CONMED recently issued a recall of its STAT 2 IV Gravity Flow Controllers because of inaccurate or inconsistent flow rates (attached). As such, all agencies should be aware of this recall and remove these devices from circulation immediately.

Parallel and independent to this recall, an unpublished study being performed by the Division of Prehospital Medicine in the last few weeks has identified that 5 commonly available rate control devices (alternatively known as a "Dial-A-Drip"), including the STAT 2 device, were all found to provide highly variable, inaccurate, and inconsistent flow rates at hanging heights commonly used by EMS providers.

Regional policy has made an expectation that vasoactive medications, specifically norepinephrine, be administered using a rate control device. In light of this recall and our initial review of performance data of other devices, ***rate control devices are no longer required for non-Specialty Care Transport vasoactive medications*** as the potential for harm or erroneous dosing exceeds the potential benefit.

Agencies should discuss options with their agency Medical Director, however at this time I am recommending using a 60 gtt tubing and mixing norepinephrine in a manner consistent with the resource provided in the Collaborative Protocols which can be found in the Appendix > Medication Infusion, then scroll down to the bottom (Also attached to this advisory). In short, remember the rule of 4's: 4 mg norepinephrine in 1 liter NS will provide 4 mcg/mL, thus 1 drop per second will be 4 mcg/min, 2 drops per second 8 mcg/min, 3 drops per second 12 mcg/min and so forth. Importantly, please use 60 gtt tubing to reduce the risk of a rapid inadvertent infusion; CLEARLY label the bag that contains norepinephrine; and as always, titrate the medication to clinical effect – either mental status or MAP >65 mmHg.

As alternatives for safely controlling vasoactive infusions are identified, they will be shared with the EMS community, however in the meantime careful infusion using 60 gtt tubing is desired. With any questions, please do not hesitate to contact this office.

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Emergency Medical Products, Inc.
Specializing in the Sale and Service of pre-hospital equipment and supplies

September 1, 2017

[redacted]

Customer Number: [redacted]

Re: CONMED Recall - STAT 2® I.V. Gravity Flow Controllers

Dear Medical Inventory Controls/Supplies Coordinator/Buyer: 10207962

This letter pertains to a device recall. If you are not the intended recipient of this correspondence, please ensure this reaches the individual/department responsible for stocking and distributing supplies within your organization.

Emergency Medical Products (EMP) was recently advised about a CONMED recall for STAT 2® I.V. Gravity Flow Controllers. This recall includes EMP number numbers S2-12 and S2V-20. All STAT 2® I.V. Gravity Flow Controllers manufactured between April 27, 2012 and April 12, 2017 are included in this action. The affected lot code range is provided below. Our records indicate that you may have purchased one of these items.

Catalog Number	Beginning Manufacture Date	Beginning Lot Code	Ending Manufacture Date	Ending Lot Code
S2-12	April 27, 2012	120427X	March 13, 2017	201703134
S2V-20	April 27, 2012	120427X	April 7, 2017	201704074

The attached letter explains the recall has been issued because CONMED has received complaints of some devices exhibiting inaccurate or inconsistent flow rates. It was determined that certain devices were assembled with an incorrectly-dimensioned supplier component. This could cause the device to exhibit inaccurate inconsistent flow rates.

Should you determine your inventory contains affected product, please set it aside and contact our Customer Service department at 800-558-6270 to arrange for return. All returns must be received at EMP within 60 days of the date on this letter.

If you have questions pertaining to the recall, you may contact CONMED at 800-448-6506.

We apologize for any inconvenience this action may cause. Thank you for allowing EMP to be your source for emergency medical supplies and equipment.

Sincerely,

Erin Northrop

Erin Northrop
Regulatory Affairs

Enclosures

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WEBSITE: www.buyEMP.com

URGENT: DEVICE RECALL

CONMED Corporation STAT 2® I.V. Gravity Flow Controllers

June 16, 2017

CONMED Corporation is sending this communication to notify you of a product issue with the following catalog numbers. Certain lot codes of the STAT 2® I.V. Gravity Flow Controllers are affected.

Catalog Number	Device Name
S2	STAT 2® I.V. Controller
S2-12	STAT 2® Extension Set Gravity Flow Controller, 12" length
S2-12 N	STAT 2® Extension Set Gravity Flow Controller (Needle-Free), 12" length
S2V-20	STAT 2® Primary Administration Set Gravity Flow Controller, 20 Drops/ml, 84" length
S2V-20 N	STAT 2® Primary Administration Set Gravity Flow Controller (Needle-Free), 20 Drops/ml, 84" length
S2-20 MD	STAT 2® Secondary Set Gravity Flow Controller, 20 Drops/ml, 13" length
S2V-60	STAT 2® Primary Administration Set Gravity Flow Controller, 60 Drops/ml, 84" length
S2V-60 N	STAT 2® Primary Administration Set Gravity Flow Controller (Needle-Free), 60 Drops/ml, 84" length

The STAT 2® I.V. Gravity Flow Controllers and Extension Sets are sold as sterile (fluid-path only), single use devices. CONMED has received complaints of some devices exhibiting inaccurate or inconsistent flow rates. It was determined that certain devices were assembled with an incorrectly-dimensioned supplier component. This could cause the device to exhibit inaccurate or inconsistent flow rates.

If the device is unable to regulate flow, as set and confirmed by the attending medical staff, and the delivery of essential medications or treatment is dependent on the device's function, this may result in possible injury to the patient. In no instance, has it been reported to CONMED that inconsistent flow rate has resulted in illness or injury.

Based on this information, CONMED has decided to recall the devices listed on Attachment I to the user level. **Therefore, do NOT use any STAT 2® I.V. Gravity Flow Controllers manufactured between April 27, 2012 and April 12, 2017.** The affected lot code range is provided on Attachment I.

These products were distributed between June 5, 2012, and April 14, 2017.

Step 1: Please review your inventory for any of the devices listed on Attachment I.
We ask that you contact all of those departments within your facility and any other facilities within your organization that may have received affected products. It is imperative that all end users of these devices receive this notice and respond immediately.

ATTACHMENT I
PRODUCT LOT CODES
MEDICAL DEVICE RECALL

Affected catalog numbers and lot codes:
Lot codes for product manufactured starting April 27, 2012 and including the dates listed below:

Catalog Number	Beginning Manufacture Date	Beginning Lot Code	Ending Manufacture Date	Ending Lot Code
S2	April 27, 2012	120427X	February 1, 2017	201702014
S2-12	April 27, 2012	120427X	March 13, 2017	201703134
S2-12 N	April 27, 2012	120427X	April 12, 2017	201704124
S2V-20	April 27, 2012	120427X	April 7, 2017	201704074
S2V-20 N	April 27, 2012	120427X	November 7, 2016	201611074
S2-20 MD	April 27, 2012	120427X	January 2 2017	201701024
S2V-60	April 27, 2012	120427X	March 16, 2017	201703164
S2V-60 N	April 27, 2012	120427X	February 13, 2017	201702134

Lot codes on boxes and packaging contain a lot code in the following form:

2014 10 01 X
2014 10 01 X
Or 14

- Manufacturing shift code 1, 2, 3, 4,5,6 or 9
- Day of the Month
- Month (October)
- Year (2014)

(4-5) Resource: Medication Infusion

Amiodarone: 150 mg in 100 mL normal saline = 1.5 mg/mL

Infusion Rate	Admin Set: 10 drops/mL	Admin Set: 15 drops/mL
10 mL/min (over 10 min)	100 drops/min or 5 drops every 3 seconds	150 drops/min or 5 drops every 2 seconds

Lidocaine: 200 mg in 100 mL normal saline = 2 mg/mL

Infusion Rate	Admin Set: 60 drops/mL
1 mg/min	30 drops/min
2 mg/min	60 drops/min
3 mg/min	90 drops/min
4 mg/min	120 drops/min

Epinephrine: 1 mg in 1000 mL normal saline = 1mcg/mL
(Must use pump or dial-a-flow)
Either concentration of epinephrine may be used to make the solution

Infusion Rate	Admin Set: 10 drops/mL	Admin Set: 15 drops/mL	Admin Set: 60 drops/mL
1 mcg/min	10 drops/min	15 drops/min	60 drops/min or 1 drop/sec
2 mcg/min	20 drops/min	30 drops/min	120 drops/min or 2 drops/sec
4 mcg/min	40 drops/min	60 drops/min	240 drops/min or 4 drops/sec
6 mcg/min	60 drops/min	90 drops/min	360 drops/min or 6 drops/sec
8 mcg/min	80 drops/min	120 drops/min	480 drops/min or 8 drops/sec
10 mcg/min	100 drops/min	150 drops/min	600 drops/min or 10 drops/sec

Magnesium:
2 grams in 100 mL normal saline = 20 mg/mL; give 100 mL over 10 minutes
4 grams in 100 mL normal saline = 40 mg/mL; give 100 mL over 20 minutes

Infusion Rate (2 grams over 10 min)	Admin Set: 10 drops/mL	Admin Set: 15 drops/mL
10mL/min	100 drops/min	150 drops/min
Infusion Rate (4 grams over 20 min)	Admin Set: 10 drops/mL	Admin Set: 15 drops/mL
5 mL/min	50 drops/min	75 drops/min

Norepinephrine: 4 mg in 4 mL mixed in normal saline 1000 mL = 4 mcg/mL

Infusion Rate	Admin Set: 10 drops/mL	Admin Set: 15 drops/mL	Admin Set: 60 drops/mL
2 mcg/min	5 drops/min	7drops/min	30 drops/min
4 mcg/min	10 drops/min	15 drops/min	60 drops/min or 1 drop/sec
6 mcg/min	15 drops/min	22 drops/min	90 drops/min or 1.5 drops/sec
8 mcg/min	20 drops/min	30 drops/min	120 drops/min or 2 drops/sec
10 mcg/min	25 drops/min	37 drops/min	150 drops/min or 2.5 drops/sec
12 mcg/min	30 drops/min	45 drops/min	180 drops/min or 3 drops/sec
14 mcg/min	35 drops/min	52 drops/min	210 drops/min or 3.5 drops/sec
16 mcg/min	40 drops/min	60 drops/min	240 drops/min or 4 drops/sec
18 mcg/min	45 drops/min	67 drops/min	270 drops/min or 4.5 drops/sec
20 mcg/min	50 drops/min	75 drops/min	300 drops/min or 5 drops/sec