14998 W. 6th Ave., Suite 830
Golden, Colorado 80401

UPDATED: URGENT MEDICAL DEVICE RECALL

Includes specific information on clinical impact and additional instructions for customers.

CME America BodyGuard® Infusion Pump System

April 27, 2020

Product Description	Model Numbers	S/N
CME America BodyGuard Infusion Pump System including Pumps, Administration Sets and Accessories	All models of BG 323, BG 121, BG545,* BG CV545, BG 575,* BG CV575, and CMExpress *Note: BG545 and BG575 pump models were inadvertently left off of the prior Customer Notification. These pumps are included in this recall.	All

For the Attention of: Recall Coordinator, Director of Nursing, Director of Purchasing, Director of Risk Management, Clinicians.

CME America (CMEA) notified customers of a voluntary Medical Device recall for the BodyGuard Infusion Pump System in a letter dated January 6, 2020. These pumps were distributed beginning in March 2009. Our records indicate that you have received one or more of the CME America BodyGuard Infusion Pump devices or their administration sets / accessories.

Description of the Problem:

The current labeling for the BodyGuard Pump indicates a flow rate range of 0.1–1200 mL/h, and an accuracy of ±5%. CMEA has recently completed internal testing to evaluate the flow rate accuracy across the labeled flow range. **Results indicate that pumps may have a delivery inaccuracy of up to 13%** (see Appendix A below).

In the January 2020 recall notice, CMEA has provided updated flow rate accuracy information. We are now providing more detailed information on the performance of the device for specific flow rate ranges to inform your decision-making. We are also updating the list of recommended actions (section "Please Read and Take Actions" below) for customers and clinicians as result of that performance variation. Depending on your therapy needs, if higher accuracy is required, we recommend considering an alternate infusion device.

Recommendation on Further Product Use:

CMEA has assessed the potential risks associated with these issues and determined that the BodyGuard Infusion Pump may be appropriate to be used in certain situations in accordance with the Operator's Manual and the additional mitigations outlined in this letter until the pumps have been removed from the market.

> **Important**: The BodyGuard Infusion Pump System **is not indicated** for the infusion of blood, blood products, or life-sustaining medications where under-delivery, or over-delivery could cause serious injury or death.

CME America has made the difficult business decision to suspend any further distribution of the BodyGuard Infusion Pump System until further notice and to remove all existing BodyGuard products from the U.S. market. (See Attachment 1 for listing of BodyGuard Infusion Pump System accessories, components, sets and pumps). We will work with your Healthcare Facility to facilitate a smooth transition away from the product, bearing special consideration for your facility's response to the COVID-19 pandemic.

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In an effort to maintain continuity of care during the pandemic CME America will maintain the following:

- Product service and repair activities through CME America and authorized service providers; however, if the infusion pump is beyond repair it is recommended that an alternative product be sourced.
- A supply of infusion sets and accessories to support the Infusion Pumps remaining at your facility until the removal or disposal of pump(s) is complete.

Immediate Actions to Take (Recommendations for Clinicians and Risk Managers):

1. Share this letter with all users of the product within your facility to ensure awareness and understanding of this notice. CME America remains available for related support and clarification where needed.

2. Review the inventory of BodyGuard Infusion Pumps in your facility. Based on your facility's ability to acquire and begin using alternate infusion devices, determine if your preferred return timeframe for the BodyGuard pumps is in 1-3 months or within 3-6 months.

   NOTE: While we are indicating a phased withdrawal of these infusion pump systems, we understand the need for continuity of care while your hospital/facility considers other options for infusion therapy. Please take this into consideration when determining your preferred timeframe of returning these devices.

Please Read and Take the Following Mitigating Actions (Recommendations for Customers and Clinicians):

3. Do not use the pump to administer critical medications (e.g., vasopressors) or medications such as insulin where infusion accuracy is important. Testing indicates that pumps may have a delivery inaccuracy of up to ±13%.

4. Depending on your therapy needs, if higher accuracy is required, we recommend considering an alternate infusion device.

5. Healthcare professionals should evaluate medications, prescribed therapies and patient populations prior to utilizing the infusion pump.

6. Confirm the drip rate approximates the pump's flow rate during operation.

7. As the device can infuse at rates slower than expected at high flow rates (> 120 mL/h), clinicians administering infusions should assess the fluid container for volumes infused, volumes remaining in the container at the end of the infusion and ensure the total volume of prescribed medication is delivered. The volume to be infused may need to be re-programmed on the device to complete the infusion. Since the device can also infuse at rates faster than expected at lower flow rates, clinicians administering infusions and patients receiving infusions should know the expected duration of the infusion; if the infusion finishes earlier than expected, patients should contact their clinicians.

8. When clinically appropriate, perform periodic pump and patient monitoring to ensure that the infusion is proceeding as intended.

9. If this pump is used in a home care setting, the prescribing clinician, patient, and home health care provider should determine the appropriateness of the pump for use, and pump / patient monitoring strategies. In addition, clinicians should reinforce to patients and caregivers to promptly contact their

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healthcare professionals for guidance in case there is remaining medication volume in the container at the end of infusion or if their bags are emptying faster than expected.

10. Verify your maintenance records to confirm your pump is within one year of the last calibration. Where calibration has not occurred in the last 12 months, please contact your Authorized Service Provider to schedule a calibration as per the current Technical Service Manual:
    - BG Single-Channel devices - OP-12 Rev 10, "BodyGuard and CMExpress Service Manual"
    - BG121 Dual-Channel devices - OP-18 Rev 07 "Twins Service Manual"

11. Complete the attached Customer Response Form and return to the contact noted on the form, regardless of **whether you have any affected devices or not**, so that CMEA may acknowledge your receipt of this notification. Indicate on the Customer Response Form the quantity and models of BodyGuard Infusion Pumps, administration sets and accessories that you possess.

12. Notify CME America if your pump is malfunctioning.

13. Report any adverse health consequences experienced with the use of this product to CME America. Events may also be reported to the FDA's MedWatch Adverse Event Reporting program:
    Web: MedWatch website at www.fda.gov/medwatch
    Phone: 1-800-FDA-1088 (1-800-332-1088)
    Mail: MedWatch, HF-2, FDA, 5600 Fisher's Lane, Rockville, MD 20852-9787

Actions Taken by CME America:

1. The calibration instruction was revised on July 9, 2019 to implement a tightened tolerance at ±1% (refer to Technical Service Manual rev. 10 for OP-12 and rev. 07 for OP-18), to account for additional inaccuracies related to the administration and/or extension sets. Importantly, this may not correct all the flow rate inaccuracies described in this letter.

2. Beginning November 26, 2019, the final acceptance testing plan in manufacturing was revised to include flow rate accuracy performance verification (±5%) across the full range (minimum, nominal and maximum flow rates).

Contact Information:

Please use the contact information provided below for complaints, adverse event reports, alternative product offerings, or questions regarding this Medical Device recall.

Customer/Technical Support	877-263-0111 (Toll-Free) 8AM to 5PM MDT

We apologize for any inconvenience this issue may have caused you and remain available for any related questions or support CMEA can provide to our customers.

Sincerely,

Barak Hamdani
General Manager

Gary Holland
Quality Manager

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Appendix A

Table 1 – CMEA internal testing results*

	Calibration data (5% tolerance)						
Flow Rate (mL/hr)	0.1	1	10	25	120	500	1200
Actual Minimum	0.11 %	-3.27 %	-4.63 %	-5.58 %	-7.34 %	-9.95 %	-10.81 %
Actual Maximum	7.71 %	3.96 %	3.79 %	2.72 %	1.71 %	0.23 %	-0.83 %
99% Confidence Minimum	-2.59 %	-4.09 %	-5.63 %	-6.76 %	-9.21 %	-11.77 %	-12.97 %
99% Confidence Maximum	8.77 %	7.14 %	6.33 %	5.86 %	4.58 %	2.38 %	2.28 %
Sample Mean	3.09 %	1.52 %	0.35 %	-0.45 %	-2.31 %	-4.70 %	-5.35 %
Sample Std Dev	2.00 %	1.97 %	2.11 %	2.22 %	2.43 %	2.49 %	2.68 %

***NOTE: Flow rate accuracy testing on 30 infusion pumps was executed using A120-160XPS infusion sets. Testing on additional sets is on-going.**

Infusion pump performance details (with 99% confidence intervals) and impact to running infusions:

- At 0.1mL/h, the pump can infuse *faster* than expected up to ~9%.
- From 1 to 25 mL/h, compared to the expected -5 % to +5 % flow rate accuracy, the devices could have the following approximate performance:

  At 1 mL/h: -4% to +7%
  At 10 mL/h: -6% to +6%
  At 25 mL/h: -7% to +6%

- At 120 mL/h, the pump can infuse *slower* than expected up to ~9%.
- From 500mL/h to 1,200 mL/h, the device can show a *slower* than expected delivery up to ~13%.

Health Hazard(s):

- Infusions running slower than expected (under infusions) can lead to remaining fluid at the end of infusion for intermittent infusions or reduced clinical effect during continuous infusions.
- Infusion running faster than expected (over infusions) can lead to bags or containers emptied faster than expected or over-infusion of medication during infusion.
- There have been no reports to date of adverse event or injury related to this issue.

  Depending on the medication being infused, over-infusions or under-infusion may cause serious adverse health consequences or death.

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CUSTOMER RESPONSE FORM

MMS-20-1906-FA2

CMEA BodyGuard® Infusion Pump System

Please assist CME America by promptly returning this form to:

Email: BDRC11@bd.com Fax No: 312-949-0333

Facility: _____

Please use full, current facility name. Do not use initials

Street Address: _____

City:_____ **State**: _____ **Zip**: _____

Contact Person: _____

Telephone No. :_____ **Email Address**: _____

Check all that apply:

☐ I have read and understood the attached notice.

☐ We do not have any affected product(s) on hand.

☐ We have the following model numbers in our inventory:

Product Name	Catalog/Model No.	Serial No.	Pump in Use (Yes/No)	Preferred Return Period (check one)	
BodyGuard Infusion Pumps				1 – 3 months	
				4 – 6 months	

Note: If the number of products in inventory exceeds the space in the table above, please include inventory list as an attachment.

You may contact CME America Customer/Technical Support @ 877-263-0111 (Toll-Free) between the hours of 8AM and 5PM MDT if you have any questions regarding this recall notification and the guidance provided.

This response form was completed by:

Name:	
Title:	
Date:	

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Attachment 1

Pumps		
Description	**Part Number**	**Product Code/ Catalog No.**
BodyGuard 121 Twins Pump	100-908PTS	100-908PTS
BodyGuard 323 Pump Systems	100-510PXSI	100-510PXSI
	100-516PXS	100-516PXS
	100-517PXS	100-517PXS
BodyGuard 323 Pump	100-603XSAP	100-603XSAP
BodyGuard 545 Pumps	100-727PXS	100-727PXS
	100-743XI	100-743XI
	100-919PX	100-919PX
	100-919PXIS	100-919PXIS
BodyGuard 545 ColorVision Pump System	100-610PXCV	100-610PXCV
BodyGuard 575 ColorVision Pump System	100-615PXCV	100-615PXCV
Bodyguard 575 pump	100-729PXS	100-729PXS
CMExpress Pumps	100-500PX	100-500PX
	100-500PXT	100-500PXT
	100-500PXA	100-500PXA
CMExpress Pump System	100-500PXE	100-500PXE

Infusion Sets		
Description	**Part Number**	**Product Code/ Catalog No.**
BodyGuard BodySet	A76.8200	A120-160SAS
BodyGuard Microsets	A76.8133	A120-160XPS
	A76.8134	A120-161XPSV
	A76.8140	A100-163XESV
	A76.8142	A100-163XES
	A76.8146	A120-161XPS
	A76.8148	A120-160XSFK
	A76.8150	A120-112XSFK
	A76.8160	A100-163XE90S
	A76.8161	A100-163XSFL
	A76.8162	A100-163XSL
	A76.8165	A120-003XS2YV
	A76.8168	A120-125XSE
	A76.8174	A120-160GCFA
	A76.8176	A120-160XYSF

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Infusion Sets		
Description	**Part Number**	**Product Code/ Catalog No.**
	A76.8179	A120-161XYB
	A76.8180	A120-161XYBS
	A76.8189	A120-160X2YB
BodyGuard Microsets with Filter	A76.8159	A100-163XESF
	A76.8163	A100-164XESF
	A76.8175	A120-160XSFE
BodyGuard Microset w/ Non-Vented Spike Connector	A76.8158	A100-163XEBS
BodyGuard Microset with Needleless Adaptor	A76.8164	A120-003XSNY
CMExpress Microbore Sets	A76.8170	A120-160CRV
	A76.8171	A120-160CYFRV
	A76.8172	A120-160CYRV
	A76.8173	A120-160C2YRV
	A76.8177	A120-161C
	A76.8178	A120-161CYF

Accessories	
Description	**Part Number**
BodyGuard ColorVision Pole-mount Charger without DC	150-313XVA
BodyGuard ColorVision Pole Mount Charger Kit	150-313XVP
BodyGuard Pole Mount Charger	150-313XU
	150-314XU
BodyGuard Pole Mount Charger Kit	150-314XUP
BodyGuard 121 Pole Mount Charger with DC	150-317TS
Bolus Button Cables	140-000X
	140-100X
Bolus Button Cable Kit	140-000XP
Bolus Button Cable with Light	140-300X
Bolus Button Cable with Light Kit	140-300XP
Table Top Charger Kit	150-331XP
CMExpress Pump Pole Mount Charger	150-386X
Wall Chargers	151-143XL
	151-143XLP
500ml Ultimate Lockbox Kit	190-900PXCVP

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Components	
Description	**Part Number**
1800 mAh Rechargeable Li Battery	130-050XAP
1800 mAh Rechargeable Li Battery four pack	130-050XAP4
1800 mAh Rechargeable Li-Ion Battery for ColorVision	130-050XV
30 mL Locking Case for Syringe	100-174S
30ml Lockbox for Syringe Pump	100-174SC
3600 mAh Rechargeable Li Battery	130-051XP
3600 mAh Rechargeable Li Battery four pack	130-051XP4
Ameritus 1st Pump Operators Manual	SM-0390
Assy. Pusher Charger BG	162-007X
BG121 MacroCreator2 IFU	SM-0491
BG121 Patient Guide for TwinCon041	SM-0494
BG121 Quick Reference Guide for TwinCon041	SM-0493
BodyComm 323 Software Kit	CommBG323P
BodyComm 575 Classic Software Kit	CommBG575C
BodyComm BG121 Software Kit	Comm121
BodyComm Communication Base with RS232 Connector	A150-318X
BodyComm Communication Kit	150-318XP
BodyComm88 Software CD	Comm88-CD
BodyComm94 IFU	SM-0492
BodyComm95 Software CD	Comm95-CD
BodyGuard 121 BodyComm and Macro Creator Operators Manual	SM-0472
BodyGuard 121 Clinician Quick Reference Guide (Dose Mode)	SM-0748
BodyGuard 121 Clinician Quick Reference Guide (Tri Mode)	SM-0640
BodyGuard 121 Operator's Manual – CD Version	SM-0118CD
	SM-0720CD
BodyGuard 121 Operator's Manual – CD Version Packaged	SM-0118CDP
	SM-0720CDP
BodyGuard 121 Operator's Manual – Printed Version	SM-0118HC
	SM-0720HC
BodyGuard 121 Operator's Manual – Printed Version Packaged	SM-0118HCP
	SM-0720HCP
BodyGuard 121 Patient Guide	SM-0923
BodyGuard 121 Sales Sheet	SM-0639
BodyGuard 121 Transport Sales Sheet	SM-0927
BodyGuard 323 Clinician Quick Reference Guide – 25-Step Mode	SM-0745
BodyGuard 323 Clinician Quick Reference Guide – Continuous Mode	SM-0638
BodyGuard 323 Clinician Quick Reference Guide – Intermittent Mode	SM-0744
BodyGuard 323 Clinician Quick Reference Guide – PCA Mode	SM-0746
BodyGuard 323 Clinician Quick Reference Guide – TPN Mode	SM-0743
BodyGuard 323 Operator's Manual – CD Version	SM-0115CD

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Components	
Description	**Part Number**
	SM-0115CDP
	SM-0710CD
	SM-0710CDP
BodyGuard 323 Operator's Manual – Printed Version	SM-0115HC
	SM-0115HCP
	SM-0710HC
	SM-0710HCP
BodyGuard 323 Patient Guide	SM-0641
BodyGuard 323 Sales Sheet	SM-0637
BodyGuard 545 ColorVision Operator Manual	SM-0406
	SM-0515
BodyGuard 575 ColorVision Operator Manual	SM-0407
	SM-0516
BodyGuard ColorVision Battery	400-202XBVAP
BodyGuard ColorVision BodyComm Operators Manual	SM-0410
BodyGuard ColorVision BodyComm Software Kit	CommCVP
BodyGuard ColorVision Macro Creator Operators Manual	SM-0411
Bolus Label For Large Lock Box	190-210X
CME Lockbox Rear Label	SM-0531
CMEAmerica Lockbox ID Label	SM-0530
CMExpress Clinician Quick Reference	SM-0931
CMExpress Clinician Quick Reference Guide	SM-0597
CMExpress Operator's Manual – CD Version	SM-0119CD
	SM-0119CDP
CMExpress Operator's Manual – Printed Version	SM-0119HC
	SM-0119HCP
CMExpress Patient Guide	SM-0592
	SM-0932
CMExpress Sales Sheet	SM-0929
ColorVision Epidural Clinician Quick Reference Guide	SM-0896
ColorVision Epidural Patient Guide	SM-0895
ColorVision PCA Clinician Quick Reference Guide	SM-0909
ColorVision PCA Patient Guide	SM-0908
ColorVision Sales Sheet	SM-0904
DC Cable	196-000XP
Disposable Battery Pack, 9V	130-050X2
Disposable Battery Pack, 9V x 2	130-050X2P
FTDI RS232 Cable	SDC-02
Hospital Power Cord	CL60106
	CL60106P

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Components	
Description	**Part Number**
Locking screw for Lock Box	F190-118X
M3 Acorn Nut for Lock Box	400-122x
Open Hook For Lock Box M3	190-107XA
Operations Manual BG545	100-094X
Operations Manual BG575	100-095X
Operations Manual CMExpress	SM-0373
PMI BodyGuard 121 Sales Sheet	SM-0922
PMI BodyGuard 323 Sales Sheet	SM-0920
PMI CMExpress Sales Sheet	SM-0930
PMI ColorVision Sales Sheet	SM-0921
Rechargeable Polymer Battery, 1800mAh	130-050XA
Rechargeable Polymer Battery, 3600mAh	130-051X
Replacement key for Lockbox	190-115XP
Replacement keys for Lockbox	190-120UP
Replacement Lockbox Keys	190-115X
Replacement Ultimate Lockbox Keys	190-120U
RS232 Cable	SDC-01
	SDC-01P
RS232 Extension Cable Male to Female	SDC-03
Standard Power Cord	SPC-01
	SPC-01P
Ultimate Lockbox Bag Hook	190-934XCV
Ultimate Lockbox Black Knob	190-955XCV
USB to Raw IR Adaptor	SIRC-01
	SIRC-01P
User Manual for NeoFeed (SW version NeoFeed_1A)	SM-0344
VisionComm Operators Manual	SM-0479
VisionComm Software CD	VisionComm-CD