

URGENT MEDICAL DEVICE CORRECTION

CME America BodyGuard® Infusion Pump System

January 6, 2020

Product Description	Catalog Number	Serial Number
CME America BodyGuard® Infusion Pump System	All models of BG 323, BG 121, BG CV545, BG CV575, and CMExpress	All

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

CME America (“CMEA”) is conducting a voluntary Medical Device recall for all BodyGuard® Infusion Pump systems. This product was distributed beginning in March 2009. Our records indicate that you have received one or more of the CME America BodyGuard® Infusion Pump devices.

Description of the Problem and Health Hazard(s):

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 Table 1 below).

Table 1 – CMEA internal testing results

Calibration Tolerance / Flow rate *99% Confidence Interval	0.1 mL/hr	120 mL/hr	500 mL/hr	1200 mL/hr
±5% Calibration Tolerance (Pumps produced before July 2019)	±9%	±9.5%	±12%	±13%
±1% Calibration Tolerance (Pumps produced after July 2019)	±9%	±5%	±6.5%	±10%

Health Hazard(s):

There have been no reports to date of adverse event or injury related to this issue.

Potential Clinical Impact:

This accuracy variation, compared to the expected $\pm 5\%$, has the potential to result in:

- faster than expected drug delivery when infusing at a very low rate (0.1 mL/h), or
- slower than expected drug delivery when infusing at high flow rates (> 500 mL/h):

Our risk analysis indicates that the likelihood of harm related to this accuracy variation is improbable.

Examples:

For intermittent infusions (e.g., antibiotic infusion, chemotherapy and TPN), this accuracy variance could result in minor variation to the delivery time and, consequently, at the end of the programmed time, residual volume could still remain in the bag.

For example, when a 100 mL antibiotic infusion is programmed to be delivered in 60 minutes:

- For an accuracy of $\pm 5\%$, the 100 mL volume will be delivered within 60 min ± 3 min.
- For an accuracy of $\pm 10\%$, the 100 mL volume will be delivered within 60 min ± 6 min.

For continuous infusions (e.g., pain management): If clinicians initiate an infusion at the minimum flow rate (0.1 mL/h), this accuracy variance could result in a delivery of 0.11 mL/h (max +10% variation).

As therapy is titrated to effect or desired target, and flow rate is increased to commonly programmed rates (≥ 1 mL/h), internal testing showed the pump performance approximates to the nominal $\pm 5\%$ accuracy.

Intended Use:

The BodyGuard Infusion Pump System is an ambulatory pump designed to transfer medication and fluids intravenously. The system is intended for patients who require maintenance medications, PCA therapy, parenteral nutritional fluids, and general IV fluid therapy in hospital and home care environments. Typical applications for the BodyGuard infusion pumps include but are not limited to chemotherapy, pain management, TPN, enteral nutrition fluids, and antibiotics.

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

Recommendation on Further Product Use:

CMEA recommends that customers continue to use the BodyGuard Infusion Pump System as per intended use. CMEA has determined through the clinical risk assessment that the risk to patients is improbable.

Please Read and Take Actions:

1. As per standard clinical practice, 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.
2. 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”
3. Share this Letter with all users of the product within your facility to ensure awareness and understanding of these actions. CMEA remains available for related support and clarification where needed.
4. 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 Infusion Pumps you possess.
5. 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
6. Contact CME America at 877-263-0111, Monday thru Friday from 9am to 5pm Mountain Time, for questions regarding this action.

Actions Taken by CME America:

- The calibration instruction has been revised to implement tightened tolerance at $\pm 1\%$ (refer to Technical Service Manual rev. 10 for OP-12 and rev. 07 for OP-18)
- Beginning November 26, 2019 the final acceptance testing plan in manufacturing has been revised to include flow rate accuracy performance verification ($\pm 5\%$) 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 notification.

CME America Contact	US Contact Information
Customer/Technical Support	303-936-4545 or 877-263-0111 toll free

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,

 01/06/2020
 Barak Hamdani
 General Manager

 06 Jan 2020
 Gary Holland
 Quality Manager

Manufacturing date is located on your pump labeling per the illustration below:



Figure 1: Label on the side of the BodyGuard Pump indicating the manufacturing date as August, 1 2016.

CUSTOMER RESPONSE FORM

MMS-20-1906-FA

CMEAmerica 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. : _____ **EmailAddress:** _____

Check all that apply:

- I have read and understood the attached notice.
- We do not have any of the affected product(s) on hand.

Product Name	Catalog No.	Serial No.

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

Name:	
Title:	
Signature:	
Date:	