



2611 Commerce Way  
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Dear Valued Customer:

On June 18, 2009, Breg Inc. issued a voluntary Recall Notification letter informing you about a potential risk associated with the Power Supply that is used with the Polar Care Kodiak cold therapy unit. What follows is a list of questions and answers that may come up related to this recall.

**1. Who issued this Recall Notification?**

Breg, Inc. voluntarily issued this Recall Notification.

**2. Why is Breg issuing this Recall Notification?**

This Recall Notification is being issued due to confirmed reports of failures of the Power Supply accessory for the Kodiak cold therapy unit.

**3. What potential health hazards exist?**

A short circuit at the electrical outlet causes the circuit breaker for the specific electrical outlet to trip. Use of the Power Supply has the potential to result in shock, fire or loss of power.

**4. Has there been any injury or death related to this potential risk?**

No.

**5. What action is Breg taking?**

Breg is issuing a voluntary Recall Notification for all suspect power supply units. Additionally, we have implemented a procedure to ensure that every Kodiak unit shipped contains an effective and safe power supply. For some period of time, this will mean that 100% of the Power Supply units sent with Kodiak shipments will have been individually tested for performance. Other actions are also being taken to maintain the satisfaction and safety of our customers and product users.

**6. How do I know if my power supply is part of the replacement program?**

The recall affects all unused Power Supply units in lot code **3508, 3908, 4308, or 4808**. To determine if a unit has one of these lot codes, open the white Power Supply Accessory Box and locate the Power Supply lot code on the Power Supply unit. The Power Supply lot code can be found on the Power Supply in the lower right hand corner of the label (reference Photograph).

**Photograph**



If the lot code on the Power Supply is **3508, 3908, 4308, or 4808**, quarantine the Power Supply and do not use it.



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**7. What should I do with the recalled Power Supply units in my possession?**

Cut the wire of the unplugged transformer with scissors and discard both pieces in your electrical waste stream.

**8. Does the Recall affect other Breg cold therapy devices?**

No, only the Kodiak device is affected. The Polar Care 300 and the Polar Care 500 are not affected by this recall in any way.

**9. Do I need to contact other parties who have acquired this product from me?**

Per FDA guidance, it is necessary to notify any party in the distribution channel for Kodiak cold therapy units. This includes any party that may be distributing or dispensing the Kodiak unit en route to the final end user. This does not include the end user him/herself. Breg will notify your customers if you provide us their contact information. If you wish to personally notify your customers please include a copy of the recall notification and the return response form. Additional copies are available from Breg Customer Relations or at our website, [www.breg.com](http://www.breg.com)

**10. Do I need to recover and/or quarantine Power Supply units that have already been used?**

No. If a Power Supply unit is defective, the defect will occur upon first use. If the Power Supply unit has been used successfully it can be expected to continue working as intended. This recall does not apply to Power Supply units that have already been used successfully.

**11. Is it necessary to open the Kodiak box in order to know if the Power Supply inside is part of this Recall?**

Yes. The lot codes of the affected Power Supply units do not correspond with any code or indicator on the outside of the Kodiak box. Any Kodiak unit shipped between November, 2008 and June 10, 2009 needs to be opened for the Power Supply lot code inspection.

**12. How do I receive a replacement unit?**

You can receive a replacement unit for your Power Supply at no cost by calling Breg Customer Relations at 1-800-321-0607.

**13. How will effectiveness of this Recall Notification be handled?**

Breg, Inc. is responsible for documenting all of the information and activities associated with this Recall Notification and reporting these results to the FDA. As part of a Recall Notification, it is customary for the manufacturer (in this case Breg, Inc.) and/or the FDA to contact the distributors and sub-distributors involved in the recall to confirm the effectiveness of this action at a later date.

**14. When will this recall be complete?**

Breg, Inc. plans to have this recall completed by July 30, 2009. Effectiveness checks may be performed for several months by Breg and/or the FDA

**15. If I have additional questions regarding this Recall Notification, who should I contact?**

You may contact Breg Customer Relations at 1-800-321-0607 with any questions related to this recall notification.