

October 24, 2012

URGENT MEDICAL DEVICE RECALL **Bluephase (G2) and Bluephase 20i Dental Curing Light**

Dear Bluephase Customer,

The purpose of this letter is to advise you that Ivoclar Vivadent, Inc. is voluntarily recalling the Bluephase G2 and Bluephase 20i dental curing lights.

Reason for the Voluntary Recall: As you might have experienced with consumer electronic products (eg, computers, cameras, etc.), older generations of rechargeable battery technology have the potential to overheat during charging. As part of our ongoing and rigorous testing, we found that, in extremely rare cases, the rechargeable battery cells of the Bluephase curing light may overheat and potentially cause consequential damage.

Risk to health: To date, no injuries or property damage have occurred. This situation would likely occur due to improper handling of the battery; however, our latest battery technology for the Bluephase curing lights significantly reduces this issue. The device includes design features which make it flame resistant, however, should the battery cells overheat, it would be over an extended period of time, causing no risk to users or patients.

How to recognize if your device is affected: If your Bluephase curing light has not yet been equipped with a new, optimized battery – identified with a grey label, we will supply you with a replacement battery free of charge, along with a full one-year warranty.

Actions to be taken:

- We believe the risk of continued use to be extremely remote, however you may wish to use your Bluephase curing light with the optional “click and cure” corded operation feature.
- Please contact Ivoclar Vivadent Customer Service at 1-800-833-8481 as soon as possible and a representative will arrange to have your curing light and battery shipped to our Customer Service Center for inspection. At the same time, if you have not taken part in our handpiece exchange, we will inspect your Organic LED display to see if your handpiece is eligible to be upgraded as well.
- Your curing light and battery will be inspected and returned to you in approximately 2-4 business days.
- Please have the serial number, which can be found on the base of the charging station or on the outside of the battery, available when you call.

Product and Distribution Information: Affected products:

Product	Product Code	Serial numbers
bluephase (G2) battery	608535	00001 to 024999 and 300000 to 302988
Bluephase 20i battery	627300	<201500

Type of Action by the Company:

The battery technology for the Bluephase G2 and Bluephase 20i has been optimized already to correct this issue.

The new batteries are identifiable by a grey label.



Other Information. Please do not hesitate to contact our Customer Service department with any questions 1-800-833-8481. We ask that you acknowledge your receipt of this letter by signing and returning the enclosed acknowledgement postcard to Ivoclar Vivadent, Inc.

Thank you in advance for your cooperation. We appreciate your understanding and would like to apologize for any inconvenience caused by this issue.

Sincerely,
IVOCLAR VIVADENT, INC.
Donna Marie Hartnett
Director QA/Regulatory Affairs

Ivoclar Vivadent, Inc.
175 Pineview Drive
Amherst, NY 14228

Phone: 716-691-0010
Phone: 800-533-6825
Fax: 716-691-2285

www.ivoclarvivadent.com
mail@ivoclarvivadent.com