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Urgent Field Safety Notice

MEDICAL DEVICE CORRECTION

**Waterlase iPlus Software Field Correction
Due to Software User Interface Discrepancy**

17 June 2014

Dear Valued Customer:

Details on affected devices:

Biolase is conducting a field correction as a result of a discrepancy present in the User Interface software (version 1.7) in the **Waterlase iPlus Dental Laser System**, Part No. 7200854-XX, purchased by your facility.

The following table lists the part number(s) and serial number(s) of the units shipped to your office:

Part Number	Serial Number
7200854-02	72140153
7200854-02	72140055
7200854-02	72140056
7200854-02	72140073
7200854-02	72140074

Description of the problem:

It has recently come to our attention that during the use of iPlus units with software version 1.7, if an error occurs when in any procedure screen, the air setting will change to 1% and OFF. Unfortunately, even after the error is cleared, the air setting will erroneously remain at 1% and OFF. This can occur in any mode: Standby, Ready or Firing. If the laser is fired with the air at 1% and OFF, the water will not spray and will only drip from the handpiece.

Advise on action to be taken by the user:

You may not be aware of the air drop, but the lack of the water spray or change in the water flow rate should be quite noticeable. Please do not continue using the laser if you experience this issue. If you continue to use the laser in hard-tissue procedures, the emitted laser energy with insufficient water spray could lead to the overheating and/or burning of the tooth which can potentially lead to thermal/pulpal tooth damage. In soft-tissue waterless applications, the gum tissue may show visible signs of thermal damage but it would be short-lived and cosmetic in nature.

Whether or not you have been affected by this, we will make arrangements to resolve the issue at your office as soon as practical with no expense to you. A Biolase-trained qualified Service Technician will contact your office to schedule the software update with your Waterlase iPlus Dental Laser System.

In the meantime, should you experience an error while using your iPlus unit and notice the air drop to 1% and OFF, we have identified a simple work-around which will enable you to continue using your laser until our Field Service Engineer can install the software update. Simply, return to the “select procedure” screen and re-select your procedure to return to the previous saved setting. This process will restore the saved air setting and the air and water spray will function as you are accustomed. If you have any questions, please contact Biolase Customer Service at 1-800-321-6717.

Transmission of this Field Safety Notice:

Kindly pass this notice on within forty-eight (48) hours of receipt to all those within your organization who need to be aware of this equipment correction as well as to any organization where the **Waterlase iPlus Dental Laser System** may have been shipped, if applicable.

We apologize for the inconvenience this may cause you and your staff. Your cooperation and understanding are greatly appreciated.

Thank you for your patience, support and loyalty.

Sincerely,



VP, RA/QA