

**Urgent Medical Device Field Correction/Removal - Immediate Action
Required**

**Auriga™ 30 and Auriga™ XL 4007
Laser System**

10 April 2019

Dear Doctor,

Cc: Chairman Medical Board and relevant Head of Department

Boston Scientific is initiating a field correction for specific Auriga XL 4007 and Auriga 30 consoles. These consoles may experience a low power message due to an issue, as described below. This letter provides recommendations to the user until a field repair can be completed or a replacement console can be provided. A Boston Scientific representative will be in contact with you directly to schedule a field repair or replacement at your facility. The console can continue to be used during this time following the recommendations within this letter.

Description and Clinical Implications

The Auriga consoles in **Table 1** may exhibit faster than normal power degradation due to a potential issue with the mechanical cooling system that could lead to a low power error (1301) to be displayed on the screen as illustrated in **Figure 1**. The console is designed to stop emitting laser pulses and enters a stand-by mode after a low power error message. If this occurs, please follow the recommendations below. The most common outcome anticipated to occur is no health consequence to the patient. The worst case reported harm is a short delay of the procedure while other power settings are selected.

Figure 1: 1301 Low Power Error





Recommendations

If you experience a 1301 low power error, please note that the console may still be functional across different power settings. If the 1301 low power error occurs, please follow these recommendations:

1. If the 1301 low power error is displayed on the screen, per the Auriga user manual, confirm the message before continuing the procedure.
2. Using the green and blue arrows in the display, select a combination of power settings for Energy (mJ) and Frequency (Hz) that will enable you to successfully complete the procedure. This can be done by altering the frequency settings or energy settings by one or two increments to achieve required power, as outlined within the Auriga User Manual.
3. In the event that there is no combination of power settings adequate to complete the case, please discontinue use of the console and contact Boston Scientific as detailed below.

Next Steps

If point 3 is happening to your console, please contact Boston Scientific Field Service at 6418 8888. If your console is performing as intended, there is no need to contact Technical Support, as a Boston Scientific representative will be in contact with you directly to schedule a repair or replacement console at your facility.

Please read carefully through the enclosed Instructions. **We ask that you please confirm receipt of this notification by completing the enclosed acknowledgement form and sending it to our facility.**

We are notifying regulatory authorities of this action as required. We regret any inconvenience that this may cause and appreciate your understanding as we take the necessary steps to ensure this is resolved in an expedient and satisfactory matter. We are committed to continuing to offer products that meet the high quality standards that you expect from Boston Scientific.

Sincerely,

Name
Manager

Encl: Instructions
Acknowledgement Form

Table 1

Auriga XL 4007		
UPN	GTIN	Serial Numbers
M0068FS4007G0	08714729959106	[REDACTED]
M0068FS4007GD0	08714729958956	[REDACTED]
M0068FS4007GR0	08714729962465	[REDACTED]
M0068FS4007GZ0	08714729962595	[REDACTED]
Auriga 30		
UPN	GTIN	Serial Numbers
M0068S30G0	08714729959007	[REDACTED]
M0068S30GD0	08714729959052	[REDACTED]
M0068S30GR0	08714729962892	[REDACTED]
M0068S30GZ0	08714729963028	[REDACTED]



Urgent Medical Device Correction/Removal – Instructions

The Acknowledgement Form enclosed with this letter must be completed and returned **even if you do not have any affected units.**

1. **Immediately post this information in a visible location near the product to ensure this information is easily accessible to all users of the device.**
2. **Complete and return the Acknowledgement Form.**
Complete the enclosed Acknowledgement Form (even if you do not have any affected products).
4. Return the form to:

Email:

or

Fax to:

Please email or fax your completed form immediately.