

Field Safety Notice (URGENT)

Products lines affected:

PASCAL Synthesis and PASCAL Synthesis TwinStar
(Systems with Endpoint Management (EpM) software feature Enabled)

Date: July 15, 2016

Attn: TMLS Distribution Partner

This is an official field safety notice regarding PASCAL Synthesis (only with the EpM software feature enabled) or PASCAL Synthesis TwinStar (only with the EpM software feature enabled).

Please read the following information and take action as indicated below.

Anomaly:

TMLS has discovered an anomaly with titration, only when EpM is turned on during the titration process.

This event may occur if the user turns on EpM, turns off the Landmark (LM) function (with any EpM supported pattern) and then enters titration mode. In either single or multiple spot titration patterns, the power output upon pressing the footswitch is the same as the EpM power. The EpM power is a percentage of the power selected in the EpM control. The user would expect the power output during titration to be equal to 100% of the selected power level and may increase the power level during the titration process. When the expected tissue response is not observed, the power level resulting from titration will produce an over-power treatment when the user subsequently treats with the titration turned off.

This phenomenon only occurs on systems with Endpoint Management enabled.

There have been one incident of overpower treatment caused by this problem in the field.

With this notice - Topcon Medical Laser Systems, Inc. is issuing **additional warnings** for the end-user. Please see attached an addendum to the Operator Manual.

Requested Action:

- 1) Acknowledge the receipt of this field notice via an official acknowledgment letter.
- 2) Locate all systems with Endpoint Management software feature Enabled. Please refer to the attached spreadsheet for shipment information from TMLS of affected units.
- 3) **For ALL affected units- Inform the physician, hospital or institution of the addendum and additional warnings issued as a result of this notice.**
- 4) **Obtain signed confirmation from the end-user regarding receipt of the addendum and additional warnings.**
- 5) Send the signed confirmation from ALL end-users to TMLS, no later than **October 15, 2016**.

Record: Please complete the following record for all affected units and either fax to (408) 235-8259 or scan and email to tmlsinfo@topcon.com (Attn: Sweta Srivastava)

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ADDENDUM

This document is issued by Topcon Medical Laser Systems to release additional warnings as an addendum to the following:

- PASCAL Synthesis (532/577) Operator Manual_**DC-03299**
(Software version 1.0.0, 1.0.1, 2.0.0, 3.1.1, 3.2.0, 3.3.0, 3.3.1 and 3.3.2)
- PASCAL Synthesis TwinStar (577/638) Operator Manual_**DC-03360**
(Software version 1.0.0, 1.0.1, 2.0.0, 3.1.1, 3.2.0, 3.3.0, 3.3.1 and 3.3.2)

Warnings



“Please perform titration ONLY with EpM software feature turned ON and Landmark feature turned ON. Prior to initiating titration, please confirm that the LM indication is in Red”



“Always verify the power settings on the screen prior to pressing the footswitch”

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PASCAL Synthesis (532) or PASCAL Synthesis (577) or PASCAL Synthesis TwinStar
(Check one)

Product Serial Number: _____

Hospital or Institution: _____

____ I certify that I have received the attached addendum and I understand the additional warnings as per this addendum.

Name of Physician (Print): _____

Address: _____

Signature: _____

Date: _____

Additional Comments:

Contact Customer Care if you have questions at:
Phone: 1.408.235.8200 or Email: tmlsinfo@topcon.com