Field Correction Notice (URGENT)



Products lines affected:

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

Date: December 6, 2016

Attn: TMLS Distribution Partner

This is an official field correction 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.

Information:

Topcon Medical Laser Systems, Inc. is pleased to announce the official release of software version 3.4.0. The software version 3.4.0 includes 'enhanced code' to address the Endpoint Management issue communicated previously via Field Safety Notice, dated July 15, 2016.

This notice is to announce that all systems with Endpoint Management feature must be upgraded to software version 3.4.0.

Requested Action:

- 1) Locate all systems with Endpoint Management software feature Enabled. Please refer to the attached spreadsheet for shipment information from TMLS of affected units.
- 2) For ALL affected units- contact the customer and schedule for the software upgrade.
- 3) Obtain signed confirmation (Page 3 of this notice) from the end-user regarding receipt of the software version 3.4.0.
- 4) Send the signed confirmation from ALL end-users to TMLS, no later than March 15, 2017.

Record: Please complete the following record for all affected units and either fax to +1-925-245-7723 or

scan and email to tmlsinfo@topcon.com (Attn: Sweta Srivastava)

Field Correction Notice (URGENT)



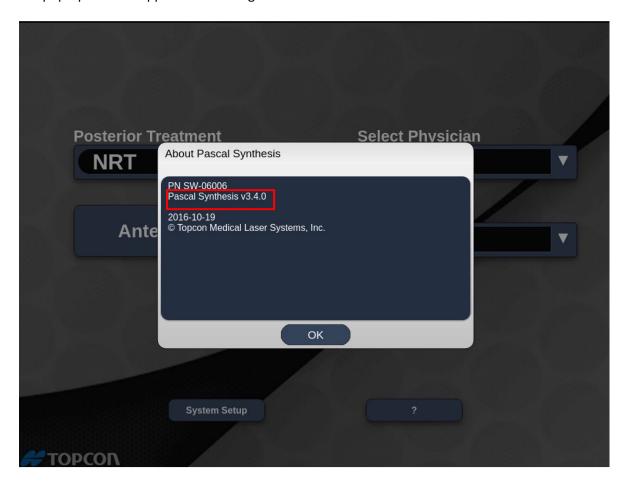
Products lines affected:

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

Date: December 6, 2016

Please confirm that software version 3.4.0 is installed on your system, by following the below steps:

- 1. Click on the Topcon logo at the bottom left of home screen.
- 2. A pop-up window appears confirming the software version.



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

Date: December 6, 2016

Please complete the following record and either fax this page to (+1-925-245-7723) or scan and email to tmlsinfo@topcon.com (Attn: Sweta Srivastava)

	PASCAL Synthesis (532) orPASCAL Synthesis (577) or PASCAL Synthesis TwinStar (Check one)	
	Product Serial Number:	
	Hospital or Institution:	
	I confirm that software version 3.4.0 is now installed on the Serial No. referenced abo and I understand the usage and functionality of this system.	ve,
	Name of Physician (Print):	
	Address:	
	Signature:	
	Date:	
Additional (Comments:	

Contact Customer Care if you have questions at:

Phone: +1.925.245.3395 or Email: tmlsinfo@topcon.com