

PRODUCT ADVISORY NOTICE

Date: 12 August 2016
Subject Device: Blue Ortho Exactech GPS Total Knee Arthroplasty Software Application
Attention: Blue Ortho Exactech GPS Users

Please be advised that the manufacturer of Exactech GPS, Blue Ortho, has issued an Advisory Notice about an issue detected on the Total Knee Arthroplasty software application.

Origin of Issue:

Blue Ortho Advisory Notice 16-0802 – Unexpected Screen Freeze, opened on 3 August 2016.

Affected Device:

Affected Device Description:	Total Knee Arthroplasty Software
Catalog Number	L00002
Software version affected:	All versions of the software application up to the last delivered version 1.15.3

Description of Issue:

When connecting the Exactech GPS Station V1 or V2 to an external mouse while using the Total Knee Arthroplasty Software application (REF L00002), if any button (middle, right or left) of the Air Mouse K10013 or K10014 is maintained pressed, then the touch screen does not function properly and freezes. The Total Knee Arthroplasty Software applications do not manage properly such use of the Air Mouse.

When releasing the mouse button, the touch screen works as expected.

Safety Impact:

If the air mouse button is maintained pressed unintentionally, this will lead to a freeze of the screen and could force the surgeon to interrupt the navigation and



revert to the conventional surgical method. This could conduct to a slight increase in the operating time.

Blue Ortho has not received any reports of injuries associated with the issue to date.

The clinical implication (Risk to Health) of the issue has been evaluated as Undesirable risk but Tolerable. No field removal is indicated.

Corrective actions undertaken by Blue Ortho:

A software update will be developed to prevent the issue and Blue Ortho will initiate its deployment on the field. The issue will be fixed in the next version of the Total Knee Arthroplasty software application.

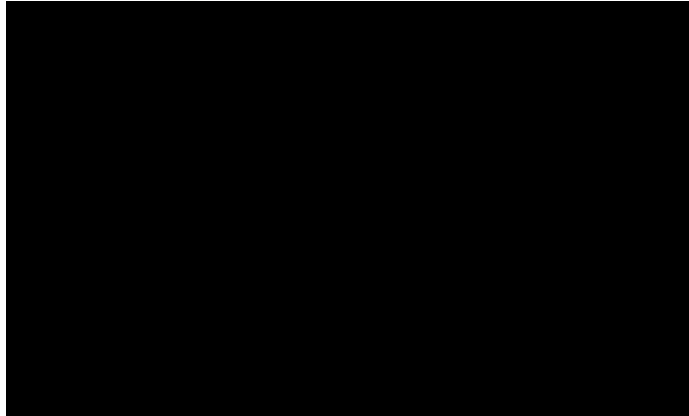
Action to be applied by user:

If the issue occurs and is detected, the surgeon or surgical staff using the mouse shall release the mouse button or remove the dongle connected to the Exactech GPS Station. Freeze of the screen should stop.

Immediate Actions Required by User:

1. Please inspect any of the subject Total Knee Arthroplasty Software application for the condition described in "Description of Issue". Our local Exactech Representative will be able to assist you in this matter.
2. Please be informed on the recommended actions as described in "Action to be applied by User".
3. Please complete and sign the attached "Acknowledgement Form". Return the form back to Exactech Pte Ltd via email (wahida.abdulrazak@exac.com.sg) or fax at **6273 1822**. Alternatively, you may submit the completed form to your local Exactech Representative.
4. Please do not remove the affected items from the premises. The use of the affected device has no safety impact to the final user or the patient.
5. Please be informed that a scheduled firmware upgrade will be arranged in due course and your organization will be notified of the installation.
6. This notice needs to be passed on to all those who needs to be aware within your organization.
7. Please maintain awareness on this notice.

Please contact your local representative for any questions pertaining to this Product Advisory Notice. Thank you for your prompt attention to this matter.



*Enclosed.
Advisory Notice by Exactech and Blue Ortho*



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ACKNOWLEDGEMENT FORM

Acknowledgement of Receipt of Field Notification:

By signing below, I acknowledge that I am aware of the issue and have been informed on the recommended actions as indicated in the Product Advisory Notice.

Printed Name: _____

Title: _____

Hospital Name: _____

Hospital Address: _____

Contact Number: _____

Signature: _____ Date: _____