

***** IMPORTANT NOTIFICATION*****

PRODUCT ADVISORY NOTICE

Date: August 5, 2016
Subject Device: Exactech GPS Station v2
Attention: Exactech GPS Users

The purpose of this letter is to inform you that an Advisory Notice is being sent by Exactech on behalf of BlueOrtho for the product in the table below.

Devices Potentially Affected: Exactech GPS Station v2

| Product Reference | Device Description |
|-------------------|-------------------------|
| I00020 | Exactech GPS Station v2 |

*All devices delivered between July and November 2014

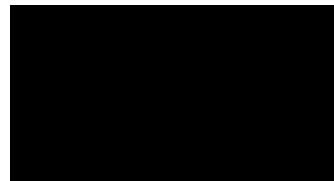
Description of Issue: Please refer to the attached notice from Blue Ortho.

Clinical Impact: Please refer to the Safety Impact stated in the attached notice from Blue Ortho.

In order to comply with applicable regulations and Exactech policies:

- Extend this information to your accounts that may have this product in their possession.
- Inspect any of the subject Exactech GPS Station v2 for the condition described in "Description of the Issue."
- Fax back or email the attached form per the Inspection Instructions.

Please note that we are required by regulation to identify accounts that have received shipment of affected inventory. The domestic and international regulatory authorities may choose to audit certain sites based on their compliance with this action. Our concern is for the health and safety of patients and the users of our products. Actions of this type are collaborative efforts and require your participation to be effective. **Please complete the attached fax back form and return it to Exactech within the next 5 working days.** Thank you for your prompt attention to this matter.



FIELD ADVISORY FAX NOTICE

Please check the appropriate box and complete as indicated.

☐

I **do not have** any Exactech GPS Station v2 (REF I00020) demonstrating the condition described in the attached BlueOrtho notice.

☐

I **have one or more** Exactech GPS Station v2 (REF I00020) demonstrating the condition described in the attached BlueOrtho notice. I will discontinue use of these devices and quarantine for returning to Exactech.

- Affected quantity of J00011 Station v2: _____
- RGA #: _____
- Tracking #: _____
(Service Provider)

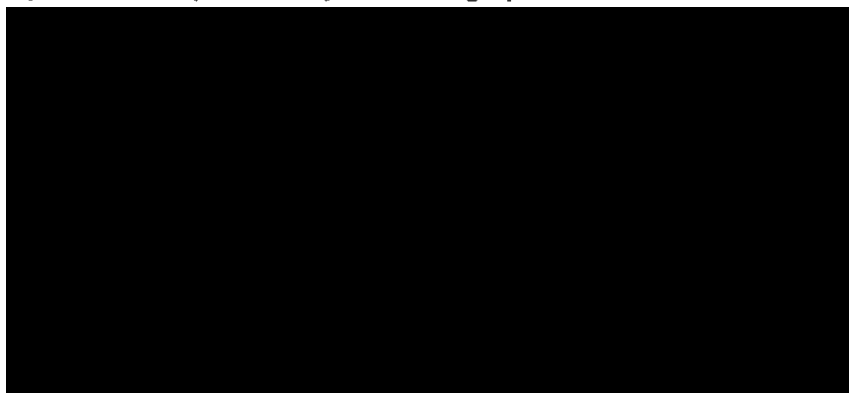
Date

Agency

Name (Print)

Name (Sign)

Thank you in advance for your prompt attention to this matter. **According to policy, please contact your Exactech inventory representative within 5 business days to confirm quantities at your location.** If you have any inventory restocking questions related to this issue, please contact Kaya Davis at



BLUE ORTHO
5 avenue du Grand Sablon
38700 La Tronche
France
Tel: +33 (0)4 76 54 95 46
Fax: +33 (0)4 76 54 95 61
Mail: info@blue-ortho.com

Exactech, Inc.
2320 NW 66th Ct.
Gainesville, FL 32653
USA
Tel: 352-377-1140

Addressed to:
Graham Cuthbert

Advisory Notice

This notice aims to inform you about an issue detected on several Exactech GPS Stations v2. By this notice, we communicate the action to undertake if you encounter this situation in your establishment.

Affected Devices:

Exactech GPS Stations v2 delivered by Blue Ortho (products reference I00020) between July and November 2014 are potentially concerned by this issue.

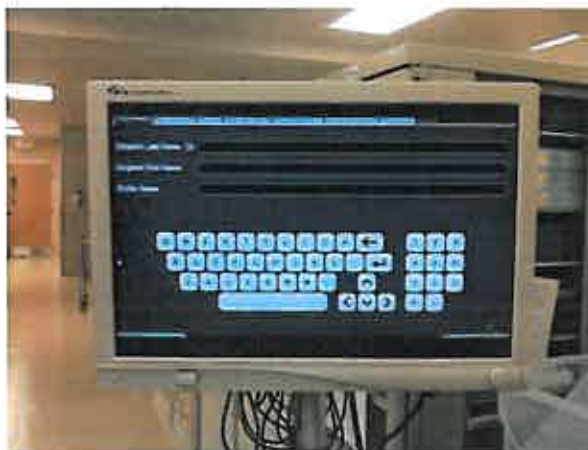
The references of the Stations V2 are the following:

| | |
|--------|--------------------------|
| I00020 | Exactech GPS Stations v2 |
|--------|--------------------------|

Description of the Issue

When connecting the Exactech GPS Stations v2 to an external display, it causes issues with the system display resolution and orientation leading to a screen rotation of the main unit.

The issue was detected in the Operating Room, as described on the pictures hereafter:



The issue is due to a wrong software configuration set up during the manufacturing of the Exactech GPS Stations v2.

Safety Impact

When there is no secondary display connected, the main screen is fully functional.

When a secondary screen is plugged, the main screen is reversed, but there is no impact on safety and effectiveness for the patient or the medical staff. If the second screen is unplugged, the main screen is fully functional in its normal orientation.

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

There is no safety impact for the patient, the final user or the medical staff:

- The issue can be identified as soon as the secondary screen is plugged, allowing the surgeon to decide if he wants to unplug the screen to restore the display on the main screen.
- From an accuracy point of view, the GPS System is still fully functional.

Corrective actions undertaken by Blue Ortho

A software patch has been developed and Blue Ortho has initiated its deployment on the field.

A servicing procedure has been issued and should be applied by authorized staff on all Exactech GPS Stations v2 impacted.

Action to be applied by the user

BLUE ORTHO recommends to not use the secondary screen functionality until the issue is solved. If this is not acceptable, ship back the Exactech GPS Stations v2 to your Exactech local correspondent.

NB: Transmission of this Advisory Notice:

- This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
- Please transfer this notice to other organizations on which this action has an impact.
- Please maintain awareness on this notice.

