

Name1
Name2
Address1
Address2

October 24, 2013

Dear OsseoCare Pro user:

This letter is to inform you about a potential malfunction of the OsseoCare Pro when used with the OsseoCare Pro iPad® application software release 1.2.0.7. The malfunction does not affect any previous software release versions.

Urgent Field Safety Notice

OsseoCare Pro iPad® app software release 1.2.0.7

Description of the problem:

When using the OsseoCare Pro iPad® application release 1.2.0.7, the grey button located on the foot pedal has no effect on the rotation direction. Pressing the grey button normally sets the motor in reverse rotation mode. However, when pressing the grey button with the software release 1.2.0.7, this does NOT change the rotation direction. The drill unit will incorrectly indicate that the reverse mode is activated with the icon on the iPad® touch screen and by the usual reverse audio alert.

The grey button on the foot pedal is mainly used in the 'Quick Drill' option in order to reverse rotation direction of screw taps and implants. Rotation speed is usually between 15 and 25 rpm.

This malfunction may result in the screw tap and/or implant being placed deeper than intended, which in the worst case could cause harm to the patient by damaging nerves or blood vessels.

A software issue in connection with OsseoCare Pro iPad® application release 1.2.0.7 has been identified as the reason for the malfunction.

Action to be taken by the user

When running the OsseoCare Pro iPad® application release 1.2.0.7, please use only the reverse button on the iPad® touch screen to reverse drill rotation. Do NOT use the grey button located on the foot pedal.

Do NOT use grey button on foot pedal



Use reverse button on iPad® touch screen



The software release version affected (release 1.2.0.7) was made available 15 October 2013. In all prior releases (release version 1.0.0, 1.1.0.7, 1.1.1.3) the grey button functions as intended. As an immediate action the affected version has been withdrawn from the Apple® App Store for download.

A new version of the OsseoCare Pro iPad® application replacing release 1.2.0.7 will be available for download on the Apple® App Store as soon as possible.

In order to check which version is installed on the iPad®, start up the OsseoCare Pro iPad® application, select the 'Info' button (top right on the first screen) and verify the software version. Should you identify the affected software version use the device only in the way described in the section "Action to be taken by the user".

Alternative solution

If you do not feel comfortable using your OsseoCare Pro device until the next application is available, you can contact your local Bien-Air Dental service center to get a loan device during this period free of charge.

Local Bien-Air Dental Service Center contact details:

Please complete the attached acknowledgement form and return to address stated in the return form.

We apologize for any inconvenience in connection with this important safety measure, which aims at avoiding any harm to your patients.



Edgar Schönbacher
CEO
Bien-Air Dental SA