

FIELD SAFETY NOTICE

ER4H FIRSTAID WEB - GIPSE WEB

Medical Devices Vigilance System

Important: Safety Notice

Product: ER4H FirstAid Web and GiPSEweb (all versions)

SRN Manufacturer Code: IT-MF-000009127

Type of FSN: New

FSN notice identifier: FSN_2023_EQMS-5047

FSCA notice identifier: FSCA_2023_EQMS-5047

Type of action: HW&SW requirements update, browser version update.

Date: 18/04/2023

TO THE CAREFUL ATTENTION of:

Clinical and nursing staff, and IT service staff, and anyone using these devices.

Dear Customer,

Dedalus is issuing a Field Safety Corrective Action (FSCA) concerning ER4H FirstAid Web and GiPSEweb (all versions).

Description of the problem

It has been found that when using the FireFox viewer to view PDFs, some values (under special conditions dependent on the PDF fonts) are changed. As the devices in question allow the PDFs of laboratory reports to be opened in this mode (although Adobe Acrobat is listed as recommended viewer), the display of an incorrect value in a report may represent a potential clinical risk for the patient.

The problem is caused by a browser bug that has been recognised by Mozilla and fixed in FireFox version 112. For these reasons, we feel it necessary to warn users that all FireFox versions below 112 are no longer supported for use with ER4H FirstAid Web, GiPSEweb devices.

Description of corrective actions

FireFox will only be supported as of version 112, Dedalus Italia SpA no longer supports earlier versions.

Dedalus staff will contact all interested customers in order to disseminate this communication.

Dedalus Italia S.p.A. con Socio Unico Dedalus Finance GmbH

Sede Legale:

Via di Collodi 6/c
50141 Firenze

Tel. +39 055 42471

Fax +39 055 451660

reception@dedalus.eu

Capitale sociale:

€ 11.634.062 i.v.

R.E.A. Firenze 591564

Codice fiscale, partita IVA
e registro imprese

05994810488

Actions required

If the browser you use is FireFox, please check the version and immediately update your browser to at least version 112.

We also ask you to acknowledge receipt of this letter as soon as possible:

1. Sign and date the attached Confirmation Form (*MOD 8.5_16.4 ER4H FirstAid Web_FSN_2023_EQMS-5047_CustomerReply_CR##*)
2. Scan and e-mail the signed form to pms.it@dedalus.eu.

Transmission of this notice

We kindly ask you to inform those who need to be aware of this notice within your organisation or any other organisation and healthcare professionals to whom the affected products (ER4H FirstAid Web and GiPSEweb) have been supplied. Please ensure that your organisation maintains awareness of this notice and the recommended steps.

Other information:

If you require further information or assistance with the critical issue described, please contact your Dedalus contact person.

We apologise for any inconvenience caused and thank you for your understanding and cooperation; it is our care to always ensure patient safety.

The signatory confirms that this Safety Notice has been notified by the manufacturer to the relevant regulatory authorities.

Sincerely yours,

Person Responsible for Regulatory Compliance

Claudia Boarini

Date: 18/04/2023

Signature: _____