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19<sup>th</sup> January 2016

## Field Safety Notice for Schiller FRED Easy AED Units

Dear Sir/madam,

I am writing to inform you that we have received a field safety notice from Schiller Medical in France in relation to the Schiller FRED Easy AED defibrillator which our records show you have purchased from us. This Field Safety Notice relates to a **CR2032** battery which is positioned on the printed circuit board of the Schiller FRED Easy AED defibrillator. This **CR2032** battery operates as a backup battery should the main battery run flat during an intervention.

We have been informed that this **CR2032** battery on the printed circuit board requires changing after six years of being in operation. For this maintenance to occur, your Schiller FRED Easy AED defibrillator unit will have to be returned to Fleming Medical. Your Schiller FRED Easy AED defibrillator will also receive a full service by us as well as any other maintenance which may be required.

Please check how long you are in possession of one of the Schiller FRED Easy AED defibrillators. If you have purchased your Schiller FRED Easy AED defibrillator prior to **January 2010**, you are affected by this field safety notice. Should you have purchased your Schiller FRED Easy AED defibrillator after January 2010, please note that you will be affected once your unit approaches being six years old. In the event that you have had your Schiller FRED Easy AED defibrillator serviced by us in the last year, you will have received a service report as per our protocols. On this report, it will be stated if the **CR2032** battery has been replaced already. If this maintenance has already been carried out on your unit, you are no longer affected.

Please feel free to contact us here at Fleming Medical should you require any more information in relation to this or if you have any concerns which you would like to discuss. Please also find attached an email from Schiller confirming the Field Safety Notice.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Anthony Holmes', with a long, sweeping underline.

**Anthony Holmes,**  
Medical Equipment Service Engineer,  
Fleming Medical Ltd.

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Dear Distributor,

As discussed in the past months, we have decided to issue a Field Safety Notice, regarding the FRED easy maintenance. The aim is to raise awareness of the operator to the importance of the replacement of the internal backup battery.

Our survey results from April 2015 showed that some FRED easy devices may have exceeded the maintenance due. This FSN is a preventive reminder for the maintenance; we didn't get any incident report for the moment.

You will find the Field Safety Notice in attachment.

We request the following actions from your side:

Declare this FSN to your local Competent Authority before January 15<sup>th</sup> 2016.

Identify the FRED easy customers.

Send, as soon as possible, the Field Safety Notice to the FRED easy owners.

Thank you in advance for your help.

For any question regarding this matter, please contact me.

Best Regards

**Alain WEISSINGER**

**Quality Manager**

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