



amazon medical

Amazon Medical Limited · Carrington Business Park · Carrington · Manchester · M31 4XL · UK
Office: 0161 776 4336 · Fax: 0161 776 4339 · www.amazonmedical.co.uk
Registered in England & Wales No. 3102071 · VAT Registration No. 639 0711 38

UK Distributor for
SCHILLER
The Art of Diagnostics

Safety Notice

Dated 29th May 2012

Product: Schiller Fred easy

Re: Transistor Error

Affected Products

All SCHILLER FRED easy devices on the market are affected.

Problem Description

Users have reported that during capacitor charging, the Schiller Fred easy very rarely displays the error message "TRANSISTOR ERROR"

Potential Risk

If this error message "TRANSISTOR ERROR" is displayed, it is sufficient to restart the Schiller FRED easy. Therefore, in the worst case, this results in a small delay in defibrillation. The probability that this error message will appear is 0.04% (0.4 per million) according to reports from the field – This risk is very low.

Requested Measures

Until the software has been updated, FRED easy devices can be used without restrictions. In the meantime restart the device if this error message is displayed.

Contact Details: Sally Turner, Managing Director Tel: 0161 776 4336
email sales@amazonmedical.co.uk

FRED easy Return form regarding safety notification

"Transistor Error"

Product	Article number
FRED easy Basic	REF BR FREDEASY
FRED easy ECG on screen	REF BR FREDEE
FRED easy Manual	REF BR FREDEEM

We confirm receipt of the safety notice regarding the FRED easy "Transistor Error"

We confirm that we have Fred easy in use *S/N's* _____

We confirm that we no longer have the Fred easy

Contact person (please use print)

Institution

Signature

Date

PLEASE SEND THIS CONFIRMATION VIA FAX TO THE FOLLOWING NUMBER:

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Safety Notice

Dated 28th May 2012

Product: Schiller FRED AED

Re: Defibrillation Electrodes – Nessler Medizintechnik
Silver packet





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Affected Product:

The affected products are defibrillation electrodes manufactured by Nessler Medizintechnik part number W1410241 & W1404262 (produced prior to January 2011) .

Problem Description

Users have reported that these electrodes, partially dry up before their expiry date has passed, thought to be due to variations in the manufacturing process.

Potential Risk

It is taken into account that electrodes dry up to a certain extent – this is compensated for by the device's impedance measurement. If the electrodes dry up even more, there is a risk that the electrodes are not detected by the machine because the impedance is too high.

Identification of Affected Product

All electrodes manufactured by Nessler Medizintechnik (silver packet) that have not passed their expiration date.

Requested Measures

Please refer to return form attached regarding this safety notification

Contact Details: Sally Turner

Managing Director

Amazon Medical Limited

Tel: 0161 776 4336

Fax: 0161 776 4339

email sales@amazonmedical.co.uk



SCHILLER FRED AED
Return form regarding safety notification

Product	Article number
FRED defibrillation electrodes Adult	REF W1410241
FRED defibrillation electrodes Child	REF W1404262
Same packet – labelled Child	

We confirm receipt of the safety notice regarding the FRED DEFIBRILLATION ELECTRODES.

We have got the above mentioned product in stock.

We require the following quantity of DEFIBRILLATION ELECTRODES Leonhard Lang GmbH to replace our NesslerMedizintechnik DEFIBRILLATION ELECTRODES with LOT/batch number:

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Product name	Article number	Required quantity
FRED defibrillation electrodes Adult	REF W1410241	
FRED defibrillation electrodes Child	REF W1404262	

We confirm receipt of the safety notice regarding the FRED pads. We do not have the above mentioned product in stock.

Contact person (please use print)

Signature

Date

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Safety Notice

Dated 28th May 2012

Product: Schiller Fred easyport, APLC1 & APLC2

Re: Defibrillation Electrodes – Nessler Medizintechnik
Silver packet





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Affected Product:

The affected products are defibrillation electrodes manufactured by Nessler Medizintechnik part number 2.155056 & 2.155057 (produced prior to January 2011), that were delivered together with the Fred easyport unit or have been acquired as an accessory.

Problem Description

Users have reported that these electrodes, partially dry up before their expiry date has passed, thought to be due to variations in the manufacturing process.

Potential Risk

It is taken into account that electrodes dry up to a certain extent – this is compensated for by the device's impedance measurement. If the electrodes dry up even more, there is a risk that the electrodes are not detected by the machine because the impedance is too high.

Identification of Affected Product

All electrodes manufactured by Nessler Medizintechnik (silver packet) that have not passed their expiration date.

Requested Measures

Please refer to return form attached regarding this safety notification

Contact Details: Sally Turner

Managing Director

Amazon Medical Limited

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**FRED easyport / APLC1/APLC2
Return form regarding safety notification**

Product	Article number
FRED easyport defibrillation electrodes Adult Same size packet as 2.155057	REF 2.155056
FRED easyport defibrillation electrodes Child	REF 2.155057
APLC1 & APLC2 defibrillation electrodes Adult	REF 0 21 0024

We confirm receipt of the safety notice regarding the FRED easyport, APLC1 & APLC2 DEFIBRILLATION ELECTRODES.

We have got the above mentioned product in stock.

We require the following quantity of DEFIBRILLATION ELECTRODES Leonhard Lang GmbH to replace our NesslerMedizintechnik DEFIBRILLATION ELECTRODES with LOT/batch number:

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Product name	Article number	Required quantity
FRED easyport defibrillation electrodes	REF 2.155056	
FRED easyport defibrillation electrodes	REF 2.155057	
APLC1 & APLC2 defibrillation electrodes Adult	REF 0 21 0024	

We confirm receipt of the safety notice regarding the FRED easyport, APLC1 & APLC2 electrodes. We do not have the above mentioned product in stock.

Contact person (please use print)	Institution
Signature	Date

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Product: Schiller Fred easy

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Affected Product:

The affected products are defibrillation electrodes manufactured by Nessler Medizintechnik part number 0-21-0000, 0-21-0003, 0-21-0020 & 0-21-0021 (produced prior to January 2011), that were delivered together with the Fred easy unit or have been acquired as an accessory.

Problem Description

Users have reported that these electrodes, partially dry up before their expiry date has passed, thought to be due to variations in the manufacturing process.

Potential Risk

It is taken into account that electrodes dry up to a certain extent – this is compensated for by the device's impedance measurement. If the electrodes dry up even more, there is a risk that the electrodes are not detected by the machine because the impedance is too high.

Identification of Affected Product

All electrodes manufactured by Nessler Medizintechnik (silver packet) that have not passed their expiration date.

Requested Measures

Please refer to return form attached regarding this safety notification

Contact Details: Sally Turner

Managing Director

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FRED easy
Return form regarding safety notification

Product	Article number
FRED easy defibrillation electrodes	REF 0 21 0003
FRED easy defibrillation electrodes	REF 0 21 0020
FRED easy defibrillation electrodes	REF 0 21 0000
FRED easy defibrillation electrodes	REF 0 21 0021

We confirm receipt of the safety notice regarding the FRED easy DEFIBRILLATION ELECTRODES.

We have got the above mentioned product in stock.

We require the following quantity of DEFIBRILLATION ELECTRODES Leonhard Lang GmbH to replace our NesslerMedizintechnik DEFIBRILLATION ELECTRODES with LOT/batch number:

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Product name	Article number	Required quantity
FRED easy defibrillation electrodes	REF 0 21 0003	
FRED easy defibrillation electrodes	REF 0 21 0020	
FRED easy defibrillation electrodes	REF 0 21 0000	
FRED easy defibrillation electrodes	REF 0 21 0021	

Contact person (please use print)

Institution

Signature

Date



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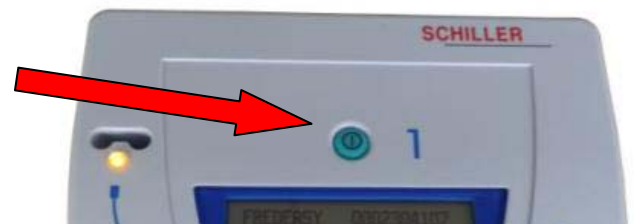
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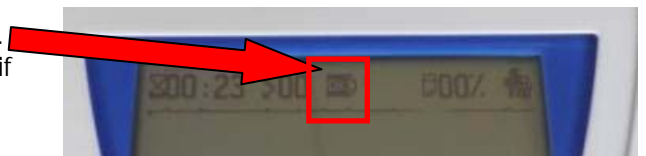
FRED easy software update using SD card

1. Please read carefully the following instructions before attempting to update your FRED easy.
2. Carefully follow the step by step instructions below.

3. Switch Fred easy on by pressing the green on/off button until the screen illuminates and text is displayed.



4. Check that the battery level displayed on the screen is « OK ». If not the battery MUST be replaced. Use your spare battery, if not available contact **Amazon Medical** your exclusive Schiller Distributor on **0161 776 4336** to order a replacement.



5. If battery shows "OK" continue, switch unit off by keeping the on/off button pressed until screen is off.

6. Remove the battery located on the right side of the device by pressing the battery latch down.



7. Remove your SD card, found under blue cover, right side of unit towards the front.
8. Push card in then release – card will pop out
9. Remove New SD card from its plastic box.
10. Insert the update SD card into the device until it clicks in place.



Continue with Instructions on page 2



11. Turn the device vertically, with battery compartment upwards.
12. Insert new or existing "OK" battery quickly, pushing firmly into place until the latch clicks, securing the battery into place.



13. Once the battery is inserted Fred easy starts automatically. The percentage found at the bottom of the screen indicates the update is in progress.



14. Wait until the message "SUCCESS ! 100%" is written on the last line of the screen.



15. When "SUCCESS ! 100%" is displayed, switch Fred easy off by keeping the on/off button pressed until screen turns off. **The NEW SD card should remain in the device**
16. Switch Fred easy on again by pressing the on/off button until the screen illuminates with text displayed.
17. Check that the chronometer (clock) has started.



18. Switch unit off by keeping the on/off button pressed until screen turns off.
19. Check that the green ready light is blinking.



20. Return the device to its location.

PLEASE NOTE : This SD card allows for one single update only. Once the update is done, the SD card remains in the device and will be used for recording interventions. Your old card must no longer be used, download any patient data via SAED Reader and destroy.

