Metrax GmbH • Rheinwaldstr. 22 • D-78628 Rottweil

May 2023

Field Safety Notice (FSN)

Dear Sir/Madam,

Metrax GmbH has determined that in very rare cases, upon activating the device, the following M250 HeartSave devices may suffer from a malfunction in the form of a complete loss of function. Upon activation, the devices may fail without warning and may no longer be operable.

Identification of the affected products

Name of the device	Serial numbers affected
PRIMEDIC HeartSave AS	73943100000 - 73943101601
PRIMEDIC HeartSave PAD	73944100000 - 73944101586
PRIMEDIC HeartSave AED	73945100000 - 73945102680
PRIMEDIC HeartSave AED-M	73946100000 - 73946101010

You can find the serial number and name of the affected devices on the silver type plate on the rear of the device, as shown in the figure.

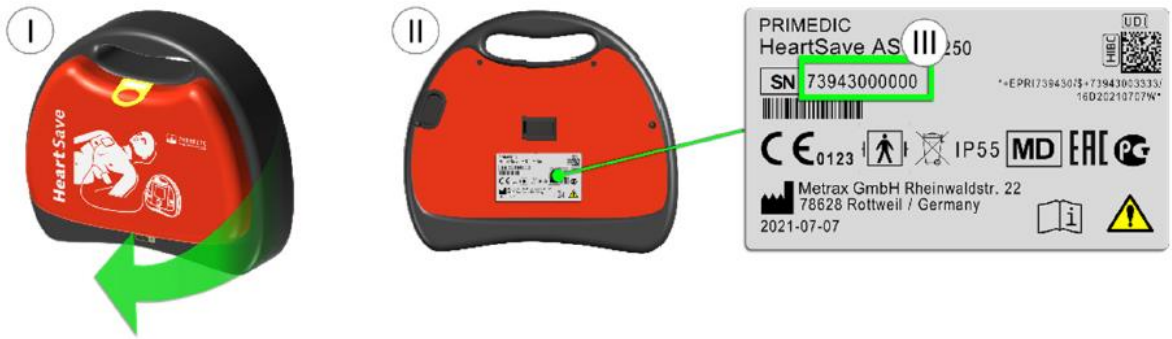

Figure 1 example: Type plate of a PRIMEDIC HeartSave AS (figure similar)

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Company Registry **Local Court Stuttgart**
HRB 470187 **ILN 4007693000009**
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Description of the possible malfunction

It is possible that upon activation, the affected devices fail to work in the form of a complete loss of function when activated, and are no longer functional upon use.

The affected devices fail sporadically when manually activated by the user or during the automatic activation in the course of the daily self-test. If the device is switched on again after failing, the monitor on the HeartSave AED-M or the LEDs on the HeartSave AED, HeartSave PAD and HeartSave AS may illuminate briefly. The device will then fail again at the same point in its activation.

A spanner symbol which appears in the status display is the visual signal that the device is no longer functional.

Risk to patients, users or third parties if use of the product continues

As the functionality of the device can no longer be guaranteed, it may be the case that no treatment can be carried out with the respective HeartSave device. The unit indicates visually that it is not functional, however, with the spanner symbol in the status display.

At present, nothing has occurred as a result of this error pattern which has led to a danger to patients, users or third parties.

Further use of devices until the completion of corrective measures

Please check the status display immediately after receiving the FSN in order to be able to recognise possible limitations of the functionality at an early stage. Please then check the status display of your device at regular intervals as described in the instructions for use until the software update has been successfully carried out.

If the status display shows “OK”, the units can continue to be used (fig. 2). If the spanner symbol is displayed in the status display, however, the devices may no longer be used (fig. 3).

Figure 2 Device ready to use

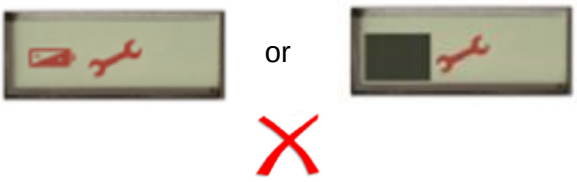

*Figure 3 Device **not** ready for use*

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Measures to be taken by the operator/user

If you are the user or operator of one or more affected devices, please proceed as follows:

1. Please confirm that you have received this letter using the enclosed confirmation form (Annex I) as quickly as possible, but at the latest two weeks after receiving this Field Safety Notice:

2. Please ensure that all persons who need to be informed are informed about this Safety Notice. To do this, please forward this letter.

3. To rectify a possible functional failure, Metrax GmbH will provide the software update on an Update-SaveCard. You will receive the Update-SaveCard by post.

4. With the delivery of the Update-SaveCards, you receive a letter with a link to the software update instructions on our homepage.

4. To perform the software update, follow the software update instructions.

5. Please confirm that the software update has been carried out using the confirmation form in the software update instructions as soon as possible, but at the latest two weeks after receipt of the software update.

Measures to be taken by the retailer:

If you are a retailer of one or more affected devices, please proceed as follows:

1. Please confirm that you have received this letter using the enclosed confirmation form as quickly as possible, but at the latest, two weeks after receiving this Safety Notice:

2. Please ensure that all your customers, as well as other people to be informed who have received one or more affected devices from you, have been informed about this Safety Notice. To do this, please forward this letter to your customers.

3. To rectify a possible functional failure, Metrax GmbH will provide the software update on an Update-SaveCard. You will receive the Update-SaveCard by post. With the delivery of the Update-SaveCards, you receive a letter with a link to the software update instructions on our homepage.

4. Please forward the Update-SaveCard with the link to the instructions to your customers.

5. To perform the software update, follow the software update instructions.

6. Please confirm that the software update has been carried out using the confirmation form in the software update instructions as soon as possible, but at the latest two weeks after receipt of the software update.

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Metrax GmbH would like to apologise for the inconvenience that this has caused, and to thank you for your support and cooperation with implementing this measure.

If you have any further questions about this Field Safety Notice, we are happy to help you if you contact us via the following:

Point of contact at Metrax GmbH regarding this Field Safety Notice:

Contact: Heiko Borkowsky

Telephone number: +49 741 257 223

Fax number: +49 741 257 200

E-mail address: vigilance@primedic.com

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PRIMEDIC
Saves Life. Everywhere.

Confirmation form – Field Safety Notice

With your signature, you confirm the following:

1) We have read and understood the Field Safety Notice.

2) We confirm that all persons in our organisation/company who need to be informed about this Field Safety Notice have been informed.

3) If you have resold or passed on the devices:
We confirm that all customers who received one or more affected devices from us have been informed about the Field Safety Notice and that the Field Safety Notice has been forwarded.

Please fill out the following table:

Organisation/company:	
Street	
Postcode/town:	
Country:	
Responsible person (point of contact)	
Telephone number	
E-mail address	
Affected device(s) with serial number(s):	

Date/signature: Company stamp

_____

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