Medset Medizintechnik GmbH

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FSCA-Ref.: CAPA 25-255

Date: May 4, 2026

Urgent Field Safety Notice
Field Safety Corrective Action (FSCA)

ECG Mobile by CardioShield (CS-281)

For the attention of: Users, physicians, healthcare professionals, distribution partners

Dear Sir or Madam,

Medset Medizintechnik GmbH wishes to inform you about an important Field Safety Corrective Action (FSCA) regarding the above-mentioned product. Medset is acting in its role as importer on behalf of and in coordination with the manufacturer Suzhou Beneware Medical Equipment Co., Ltd.

During internal quality checks, a deviation was identified that may affect the display of ECG signals. To date, no incidents or patient harm related to this deviation have been reported. This action is being taken as a precautionary measure to ensure patient safety.

Your immediate action is required:

1. Immediately cease use of all affected ECG Mobile devices until the required firmware update has been performed.
2. Critically review ECG recordings previously made with the affected devices (see attached FSCA for details).
3. Send the attached response form to **siba@medset.com** without delay to confirm receipt of this notice and to schedule the update.

A detailed description of the problem, the clinical implications and the actions to be taken can be found in the attached FSCA.

Should you have any questions, please contact Ms Manuela Hoffmann at **siba@medset**.com or by phone at **+49 40 725 822-58.**

Medset has notified the Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) about this action.

Yours sincerely,

Manuela Hoffmann
Corporate Development & PRRC
Medset Medizintechnik GmbH

Urgent Field Safety Notice
Field Safety Corrective Action (FSCA)

FSCA-Ref.: CAPA 25-255

ECG Mobile by CardioShield

Temporary Cessation of Use Pending Firmware Update

Date: May 4, 2026

For the attention of: Users, physicians, healthcare professionals, distribution partners

Contact details for the local representative / importer

Medset Medizintechnik GmbH (Importer)

Curslacker Neuer Deich 66, 21029 Hamburg, Germany

Contact person: Manuela Hoffmann

Email: siba@medset.com

Phone: +49 40 725 822-58

1. Information on the affected products

1.1 Device type

12-lead ECG amplifier for resting and stress ECG via USB

1.2 Trade name(s)

ECG Mobile by CardioShield

1.3 Unique Device Identifier (UDI-DI)

UDI-DI: 06958066402143 (GS1)

EUDAMED-DI: B-06958066402143 (Legacy Device, no Basic UDI-DI assigned)

1.4 Primary clinical intended use

Recording and transmission of 12-lead ECG signals for diagnostic purposes in cardiology, including resting and stress ECGs.

1.5 Device model / catalogue number(s)

Manufacturer model: CS-281

Medset article numbers: BAG3910-01, BAG3910-02, BAG3910Z-01

1.6 Software version

Affected ECG Mobile by CardioShield device firmware: all firmware versions currently in the field up to and including 18042024.

1.7 Affected Serial Numbers

All 36 devices on the German market are affected. The complete list of serial numbers can be found in Appendix 1 of this FSCA.

1.8 Risk class

Class IIa (according to MDD 93/42/EEC)

1.9 Manufacturer and economic operators

Manufacturer

Suzhou Beneware Medical Equipment Co., Ltd.

7F, No. 8 Building, Software Park, Suzhou Science & Technology Town, Suzhou 215163, Jiangsu, P.R. China

SRN: CN-MF-000015853

EU Authorised Representative

Shanghai International Holding Group GmbH (Europe)

Eiffestraße 80, 20537 Hamburg, Germany

SRN: DE-AR-000000001

Importer

Medset Medizintechnik GmbH

Curslacker Neuer Deich 66, 21029 Hamburg, Germany

SRN: DE-IM-000017042

2. Reason for the Field Safety Corrective Action (FSCA)

2.1 Description of the product problem

Medset identified a deviation in the above-mentioned ECG amplifier during internal quality checks. Medset is acting in its role as importer on behalf of and in coordination with the manufacturer.

Contrary to the established specification, the A/D converter of the device operates with a deviant quantisation (LSB). This results in signal amplitudes increased by up to 33 % while signal duration remains unchanged.

This action is being taken as a precautionary measure, as no incidents or patient harm have been reported to Medset to date.

2.2 Hazard leading to FSCA

Risk to patients (indirect, via misdiagnosis):

Impact on ECG morphology and interpretation: An amplitude increase of up to 33 % means that all vertical deflections (P wave, QRS complex, T wave) as well as ST segment elevations or depressions are artificially enlarged. Temporal parameters (duration) remain unchanged. As the HES algorithms operate with fixed amplitude thresholds, the erroneous, excessively high values are directly incorporated into the automated measurements.

This problem predominantly leads to **false-positive findings**. The artificially enlarged QRS amplitudes may falsely lead to a diagnosis of left or right ventricular hypertrophy. Similarly, physiological ST segments may be artificially elevated above the diagnostic threshold for ischaemia or myocardial infarction. False-negative findings are unlikely, with the exception that a pathological low voltage (e.g. in pericardial effusion) could be masked by the artificial amplitude increase.

2.3 Probability of Occurrence

Affects every recording made with every affected device. The amplitude deviation is systematic and reproducible.

2.4 Predicted risk to patients / users

The risk is indirect in nature: there is no immediate hazard from the device itself (electrical safety), but rather from potential misdiagnosis based on distorted ECG signals. This may lead to unnecessary investigations (false-positive) or failure to detect pathological findings (false-negative).

2.5 Background Information

The deviation was identified during routine internal quality checks by Medset Medizintechnik GmbH. Medset promptly informed the manufacturer Suzhou Beneware Medical Equipment Co., Ltd. To date, no reports of incidents or patient harm related to the described problem have been received.

3. Type of risk mitigation measure

3.1 Measures to be taken by the user

- **Identify the device**
- **Isolate/quarantine the device**
- **Follow patient management recommendations**

Cease use: Immediately discontinue all examinations with the affected ECG recorders (ECG Mobile) until the required firmware update has been performed.

Identification and isolation: Identify the affected devices in your facility and ensure that they are not used for patient care until the correction has been applied.

Review of previous recordings: We strongly recommend that you critically review ECG findings previously recorded with the affected devices, taking into account the error pattern described above (in particular newly diagnosed hypertrophies or indications of ischaemia). Please assess at your clinical discretion, and considering the overall clinical picture, whether affected patients should be recalled for a follow-up examination with an error-free ECG device to confirm the diagnosis.

3.2 By when should the measure be completed?

The cessation of use must be implemented immediately. The response to Medset should be sent without delay, at the latest within 14 days of receipt of this FSCA.

3.3 Follow-up of patients

A review of previous findings is recommended (see 3.1). The decision on whether to recall patients lies at the physician's clinical discretion, taking into account the overall clinical picture.

3.4 Is a response from the customer required?

Yes. Please complete the attached response form and send it to **siba@medset.com** to confirm receipt of this notice and to schedule the update.

3.5 Measures taken by the manufacturer/importer

A firmware update of the device is required and can be performed immediately. Medset Medizintechnik is pleased to perform the update for you.

3.6 By when should the manufacturer's action be completed?

Firmware update: immediately available, to be scheduled.

4. General Information

4.1 FSCA Type

Initial field safety corrective action (Initial FSCA).

4.2 Is another FSCA expected?

No.

4.3 Manufacturer Information

See Section 1.9.

4.4 Notification to the competent authority

Medset has notified the Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) about this action.

4.5 Attachments

Appendix 1: List of affected serial numbers

Appendix 2: Response Form / Acknowledgment of Receipt

4.6 Signature

Should you have any questions, please contact:

Manuela Hoffmann

Corporate Development & PRRC

Email: siba@medset.com

Yours sincerely,

The Medset Team

Transmission of this Field Safety Corrective Action

This notice needs to be passed on to all those who need to be aware within your organisation. Please transfer this notice to other organisations to which potentially affected devices may have been supplied. Please report all device-related incidents to the manufacturer, the importer and the national Competent Authority

Appendix 1: Affected devices / devices on the market

Serial number	Item	Description
89B53A70	BAG3910-01	ECG Mobile by CardioShield
89BB8570	BAG3910-01	ECG Mobile by CardioShield
89D9EE70	BAG3910-02	ECG Mobile by CardioShield
89E41770	BAG3910-02	ECG Mobile by CardioShield
8A05D870	BAG3910-02	ECG Mobile by CardioShield
899A4970	BAG3910-01	ECG Mobile by CardioShield
89C9F770	BAG3910-02	ECG Mobile by CardioShield
89E45870	BAG3910-01	ECG Mobile by CardioShield
89F03C70	BAG3910-01	ECG Mobile by CardioShield
89E46870	BAG3910-02	ECG Mobile by CardioShield
89EFA670	BAG3910-02	ECG Mobile by CardioShield
89D72670	BAG3910-01	ECG Mobile by CardioShield
89C3E170	BAG3910-02	ECG Mobile by CardioShield
89F14A70	BAG3910-01	ECG Mobile by CardioShield
89E06970	BAG3910-01	ECG Mobile by CardioShield
89E47170	BAG3910-01	ECG Mobile by CardioShield
89F70B70	BAG3910-02	ECG Mobile by CardioShield
89C0C870	BAG3910-02	ECG Mobile by CardioShield
89EFCA70	BAG3910-02	ECG Mobile by CardioShield
89C56170	BAG3910-02	ECG Mobile by CardioShield
89E20770	BAG3910-02	ECG Mobile by CardioShield
89DA0A70	BAG3910-02	ECG Mobile by CardioShield
89E18D70	BAG3910-02	ECG Mobile by CardioShield
89B3EF70	BAG3910-02	ECG Mobile by CardioShield
89BF5170	BAG3910-01	ECG Mobile by CardioShield
89DD9E70	BAG3910-01	ECG Mobile by CardioShield
89E18770	BAG3910-02	ECG Mobile by CardioShield
89DB4E70	BAG3910-02	ECG Mobile by CardioShield
89E21770	BAG3910-01	ECG Mobile by CardioShield
8998AF70	BAG3910-02	ECG Mobile by CardioShield
89B61370	BAG3910Z-01	ECG Mobile by CardioShield, Zimmer
893B3870	BAG3910Z-01	ECG Mobile by CardioShield, Zimmer
89B66270	BAG3910Z-01	ECG Mobile by CardioShield, Zimmer
89D8EF70	BAG3910Z-01	ECG Mobile by CardioShield, Zimmer
89DED070	BAG3910Z-01	ECG Mobile by CardioShield, Zimmer
89EDC770	BAG3910Z-01	ECG Mobile by CardioShield, Zimmer

Appendix 2: Response Form / Acknowledgment of Receipt

Please fill out and send to: siba@medset.com

I confirm that I have read and understood the Urgent Field Safety Notice dated May 4, 2026.

☐ Use of the affected devices has been discontinued

☐ There are no affected devices in our facility

Name of the facility: _____

Contact person: _____

Serial numbers of the devices: _____

Date / Signature: _____