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March, 2009

## Important Security Information

### Software-Update regarding FLASHLIGHT PC-ECG for Resting- and Stress Test-ECG

#### Anrede

according to our files you have the FLASHLIGHT Software in use in a network operation with 2 or more licenses. Shortly we have been advised that an aberrance is occurring during the display of the patients list.

#### Products involved

**PADSY from Version 6.2a up to Version 6.5b  
 with FLASHLIGHT 3.8a up to 3.9a and FLASHLIGHT ERGO 2.4a up to 2.6a  
 within a SERVER/CLIENT Operation with minimum two licenses**

#### Description of the problem

When modifying the data of a patient on any workstation, all the recordings of that patient will be added on all opened patient recording lists on the „Patient sheet“. All these wrongly assigned recordings can be opened, read, edited and printed by the users.

**However the correct patient names will always be displayed in the headers and on all printouts.**

**All the stored data stay consistent.**

- Security problem** If the user opens a wrongly assigned data record without paying attention to the displayed patient name, then it can happen that the diagnosis will be allocated to the wrong patient.  
It concerns a temporary display malfunction.  
But a new risk assessment has shown that the risk for FLASHLIGHT / FLASH-LIGHT ERGO Systems within a network with more than one license is not supportable.
- Necessary actions of the user** All the users doing clinical diagnosis directly on the monitor screen must, be controlled before each ECG diagnosis will be done. It is necessary that the **correct patient name is displayed** in the upper screen bar until the installation of an update/software patch solves the problem.
- Scheduled actions by Medset** Medset is currently working on a software solution for this problem and will inform you soon about the next steps for the debugging of the problem.

**Distribution of the described information:**

Please make sure that in your organisation all users doing clinical findings directly on the monitor screen are informed about this important security information.  
If you delivered these products to third parties, please pass a copy of this information or contact the undersigned mentioned.  
Please keep this information at least until this problem is solved.  
The German institution "Bundesinstitut für Arzneimittel und Medizinprodukte" has received a copy of this security information.

If you have any question regarding this letter or the actions to be taken, please contact our technical service department:

phone: +49-40 / 725 822-40  
fax: +49-40 / 725 822-11  
Email: [service@medset.com](mailto:service@medset.com)

Thank you for your understanding and your support in this matter. Please accept our excuses for the inconveniences this may cause

Best regards

Medset Medizintechnik GmbH



Head of quality assurance

To  
Medset Medizintechnik GmbH  
Quality assurance  
Curslacker Neuer Deich 66  
21029 Hamburg

March, 2009

Fax: +49 - 40 / 725 822-11

**Letter of acknowledgement**  
**of**  
**Security Information**  
**Software-Update**  
**regarding**  
**FLASHLIGHT PC-ECG for Resting- and Stress Test-ECG**

from

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Please write down the date, when your organisation has received this security information and fax us back this acknowledgement of receipt.

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date

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name

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signature