

Hamburg, 03.05.2019

Corrective action for safety information Nr. 03868/19

Dear Sirs and Madames,

In our letter dated March 25, 2019, you received the safety information about the risk of causing patient confusion while reading several liveECG long-term recorders in case you follow a specific procedure.

We have developed a solution in the form of a new driver that can eliminate this risk. Update your PADSYS software with the new driver **livetececg-1.5.dar** according to the enclosed installation instructions.

You receive this file, an installation description and a confirmation form attached to this e-mail.

After the update, please print out the "confirmation form" and send it back to us signed. This is necessary to prove that the corrective action has been implemented.

We apologize again for the inconvenience and thank you for your cooperation. If you have any questions about the installation of the update, we will gladly support you.

Kind regards
Medset Medizintechnik GmbH



i.V. Carsten Florian
Safety Officer Medical Devices
Tel.: 040-725822-25
Fax: 040-725822-11
Mobil: 0172-9693953
E-Mail: siba@medset.com

attachement:
Livetececg-1.5.dar
Installation instruction
Confirmation form