Field Safety Notice

Use of an Isolation Transformer in combination with Sentec's Digital Monitor in home care settings

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Manufacturer:	**Sentec AG,** Ringstrasse 39, 4106 Therwil, Switzerland
Affected products:	Sentec Digital Monitors used in home healthcare environments
Product name:	Sentec Digital Monitor
REF:	SDM
UDI-DI:	07640121880018

Valued Sentec customers

Sentec is initiating a field safety corrective action to inform customers regarding a non-compliance of the Sentec Digital Monitor (SDM) with normative requirements from IEC 60601-1-11:2015 Medical electrical equipment when used in home environments.

Customer action is required; Sentec enforces the use of an isolation transformer in combination with the SDM in home care settings to comply with applicable safety standards. The isolation transformer is intended to ensure a galvanic separation of the SDM from supply voltage in home care installation settings and is thus considered as a further risk reduction measure.

Important Note: Due to the improbable risk of an incident, the use of SDMs already installed in home care settings may continue until the isolation transformers are available for upgrading the installed monitors.

Description of the non-compliance

The non-compliance is, that the SDM is a protection class I device while IEC 60601-1-11:2015 requires a protection class II device for use in the home healthcare environment. The main difference between class I and class II devices are the use and function of protective earth. Class I devices often rely on the presence of protective earth to meet all safety requirements as per IEC 60601-1 ed. 3.1. Therefore, a missing protective earth connection is considered as a single fault condition. Class II devices do not require protective earth for safe use.

In home healthcare environment, protective earth connection may not always be available.

Assessment of the electrical safety and risk assessment

Sentec's Digital Monitoring System has a long history of safe use; the SDM using the V-Sign™ Sensor for tcPCO2/SpO2 monitoring is on the market since 2003 and on the home care market since 2010. TcPCO2/SpO2 monitoring at home shows comparable or even better results to hospital recordings.

Since the device is on the market, Sentec is actively monitoring post-market data such as complaints and adverse events. Sentec estimates that over 1'000 devices brought to the market are currently used in home care environment with more than 100'000 applications per year. According to Sentec's post-market data, up-to-date, no incidents or adverse events with regard to electrical safety issues occurred – neither in home care environment nor in clinical environment. Hence, in practice, 0 (zero) occurrences of incidents/adverse events were reported of the course of more than 1'000'000 applications in home use during the last 10 years.

The residual risks related to electricity/electrical shock are addressed in Sentec's risk analysis. The benefit of monitoring patients at home outweighs the residual risks.

Description of the field corrective action

New isolation transformer

In order to be able to operate a device with protection class I in a home environment, an isolation transformer with double insulation (2x MOPP) is used, which carries out the earth connection but isolates the mains voltage. In the fault condition of the housing short circuit (main to PE), the combination of protection class I device with the isolation transformer achieves an equivalent safety as a protection class II device. This means that the requirements of the IEC 60601-1-11:2015 standard are alternatively but adequately fulfilled with equivalent safety.

The isolation transformer is intended to ensure a galvanic separation of the SDM from supply voltage in home care insulation settings and thus is further minimizing the risk. The isolation transformer will be available in two variants, which cover the voltage ranges worldwide (RFT100VA-V1 (100-120 V) and RFT100VA-V2 (230 V ± 10%)).
The SDM in combination with the isolation transformer was successfully tested by an independent testing laboratory to applicable standards for medical device, electrical safety, electromagnetic compatibility (EMC), mechanical safety and environmental temperature and humidity.

Additional instructions and new labeling documents

Three additional instruction manuals and one sticker supplement the labeling documents delivered with Sentec's Digital Monitoring System to specifically address the user groups in home care environment and define the competencies of the user groups, such as lay users and instructed person from the homecare provider:

HB-010069 Directions for Lay Users

HB-010103 Home Use Manual Instructed Person

HB-011028 Quick Guide for Installation at Home User Site

Sticker to be placed on the Sentec Digital Monitor (SDM) with the following warning: "Home use of SDM only in conjunction with Isolation Transformer. Do not make any changes to the device setup as installed by the home care provider."

The manuals and sticker listed above are provided with each isolation transformer.

You will receive more detailed information about the installation of the isolation transformer at patient's homes from your local Sentec representative.

Documents attached to this guidance document

The referenced instruction manuals and directions for use are provided through www.sentec.com/ifu. At this location, you will always find the current version of these documents.

Contact Information

Please contact your local Sentec representative (https://www.sentec.com/about-us/distributors/), if you have any questions regarding this voluntary field corrective action and/or the related products.

We apologize for any inconvenience this may cause and appreciate your cooperation. Please be assured that maintaining a high level of product quality and customer satisfaction is our highest priority.

Yours sincerely,

Caroline Möller, Ph.D.

Head of Regulatory Affairs and Quality Assurance