Urgent Safety Information

Modification of the operating instructions for the PRIMEDIC™ AkuPak LITE

Tuesday, 7th June 2016

Sender:

Norman Scholz

Rheinwaldstrasse 22

78628 Rottweil

Addressed to:

Users, operators, marketers

Identification of the medicine products concerned:

This affects the PRIMEDIC™ AkuPak LITE in the following versions:

73820 AkuPak LITE (2300mAh) 4Y

Metrax GmbH
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Internet: http//www.primedic.com

Managing Director: Tobias Mohry
Commercial Register, District Court at Stuttgart
HRB 470187 • ILN 4007693000009
Ust-IdNr | VAT.: DE811245037

73828 AkuPak LITE (2500mAh) 4Y

73910 AkuPak LITE without Charger 4Y

73975 AkuPak LITE (2500mAh) TR 2.5Y

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Description of the problem, including the determined cause:

If the PRIMEDIC™ DefiMonitor XD is stored for long periods with the PRIMEDIC™ AkuPak LITE inserted and with direct connection to the mains power via the integrated mains unit, the defibrillator is only supplied from this source in the course of the daily self-test, i.e. no power is taken from the battery inserted in the unit. This means that the battery management system (BMS) integrated in the PRIMEDIC™ AkuPak LITE will not have its residual capacity checked by a new evaluation throughout the entire period. For this reason, internal power consumption and chemical self-discharge of the cells can result in a reduction in the capacity, without starting a charging process for the PRIMEDIC™ AkuPak LITE. A new evaluation of the residual capacity will only take place when the PRIMEDIC™ DefiMonitor XD is disconnected from the mains and is switched on.

Risk to patients, users and third parties if use of the product is continued:

The greatest risk from the observed behaviour of the equipment is that the equipment signals readiness for operation although, on account of the actually reduced capacity of the PRIMEDIC™ AkuPak LITE, it is not available to the full extent, however. Internal investigations have shown that brief operation without therapy function is still possible with the PRIMEDIC™ DefiMonitor XD. Depending on the local situation, the user can regain full deployment capability of the defibrillator in this time by connecting the defibrillator to the mains power network and thus also start the charging process of the PRIMEDIC™ AkuPak LITE.

Assessment of risk/risks:

The following factors must be fulfilled simultaneously for the above case to occur:

- Storage of the PRIMEDIC™ DefiMonitor XD for several months with inserted PRIMEDIC™ AkuPak LITE
- Permanent connection to the mains power network
- No emergency deployment or other operation during this period causing disconnection of the PRIMEDIC™ DefiMonitor XD from the mains power network

The fact that the above conditions need to occur simultaneously significantly reduces the probability of occurrence of a missing therapy function of the PRIMEDIC™ DefiMonitor XD because of a discharged PRIMEDIC™ AkuPak LITE, so that Metrax GmbH assumes that there is no unacceptable patient risk. Metrax GmbH knows of no case at the present time where the patient has suffered injury based on this configuration. However, Metrax GmbH has decided to take measures to prevent any occurrence in the field. This letter is intended to inform you of these measures.

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What measures does the addressee have to take?

In a new revision of the operating instructions for the PRIMEDIC™ AkuPak LITE (English Version: MGA23140 Rev. B) Chapter 4.4.1 describes a procedure how the operator or user of a PRIMEDIC™ DefiMonitor XD can securely start charging the PRIMEDIC™ AkuPak LITE and thus effectively prevent the unnoticed discharge when storing the PRIMEDIC™ DefiMonitor XD when connected to the mains power network. This procedure consists of the following steps:

- Isolate the defibrillator from the power mains
- Switch the defibrillator on via the battery mode
- Allow the defibrillator to operate for approx. 5 minutes

The charge status of the PRIMEDIC™ AkuPak LITE is reassessed and displayed.

The new revision of the operating instructions for the PRIMEDIC™ AkuPak LITE will be available when this document is published.

Make sure that all the PRIMEDIC™ AkuPak LITE units in your possession are checked and charged in accordance with the described procedure in order to ensure their unrestricted deployment capability. In addition, you should also make sure that all persons in your organisation who are concerned with handling the PRIMEDIC™ DefiMonitor XD and PRIMEDIC™ AkuPak LITE are informed of this update of the operating instructions and are aware of the procedure for safe and secure charging of the PRIMEDIC™ AkuPak LITE.

If these measures are taken, then safe operation of the PRIMEDIC™ DefiMonitor XD and the PRIMEDIC™ AkuPak LITE is possible without any restrictions.

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Forwarding the information described here:

Please make sure that all the users of the above products in your organization and other persons who need to be informed are aware of this **Urgent Safety Information**. If you have submitted the products to third parties, then please forward a copy of this information to them or inform the contact shown below.

Please retain this information at least until the measures have been taken.

The Bundesinstitut für Arzneimittel und Medizinprodukte [Federal Institute for Drugs and Medical Devices] has been sent a copy of this "Urgent Safety Information".

Contact:

[redacted]

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