

Safety Notice

Defigard 5000

Object: Synchron Defibrillation mode.

Affected devices:

Monitor– Défibrillator DG5000 with software „Soft33“ to „Soft 35“ .

Description of the problem:

Nonsynchronous shocks have been reported by one user, while the device was configured in synchronous defibrillation mode.

This behaviour could be reproduced in laboratory, only in a particular configuration „synchro at start“: **Synchro**

In this configuration, and only if the patient is connected at the start of the device, a non optimal shock could be issued.

Identification of the affected devices:

Devices manufactured with Serial Numbers: From n°101992006538 to n° 101993008667

From n°101993100101 to n° 101994100500

Devices updated in versions „Soft33“ to „Soft35“

Software version is displayed alternately with the current time, in the upper left corner of the screen.



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Preventive measures:

Until software update in a version equal or higher than „Soft36“, the configuration synchro at start shall be : **Direct** (Factory configuration).

In this configuration, the device can be used without restrictions.

An update will be available soon, you will be kept informed.

For further information, please contact your local SCHILLER Distributor.

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