



GOLD LITE PTE. LTD.

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<Name and Address of Hospital>

<Date>

TO: WHOM IT MAY CONCERN

CC: Chairman Medical Board and relevant Head of Department

Attached is a Field Safety Notice/Field Change Order pertaining to Schiller CARDIOVIT MS-2007, MS-2010 and MS-2015. Please note that the serial number of the affected units are stated below:

Affected Serial Numbers: <serial number>

If you require any clarifications or support concerning this issue, please contact the local distributor, Gold Lite Pte Ltd, 62730487 from Monday to Friday 09:00 to 17:45.



Field Safety Notice

SCHILLER
The Art of Diagnostics

CH-FORM-0017Rev.01

Effective date:01 Jan 2018

Field Safety Notice

CARDIOVIT MS-2007; MS-2010; MS-2015
FSCA-identifier: 22.11.2018
Type of action: User Guide Change

Date: 22.11.2018

Attention: Schiller subsidiaries, distributors and customers

Details on Affected Devices:

Product	Article Number	Serial Number
CARDIOVIT MS-2007	0A.101000 3.900790 Standard 3.900792 WLAN	all
CARDIOVIT MS-2010	0.090000 3.900800 Standard 3.900805 WLAN 3.900804 WLAN /GSM	all
CARDIOVIT MS-2015	0A.100000 3.900810 Standard 3.900829 Standard 2014 3.900812 WLAN / GSM 3.900830 WLAN / GSM 2014 3.900833 WLAN	all

Device Type and Intended Use:

CARDIOVIT MS-2007/2010/2015 is an electrocardiograph (ECG) unit used for recording, analysis and evaluation of ECGs. Recording can be used as a diagnostic aid for heart function and heart conditions.

The CARDIOVIT MS-2007/2010/2015 is intended for use in hospitals, cardiological units, out-patient clinical units and general physicians' offices.

Description of the problem

Schiller has received notice that the batteries of CARDIOVIT MS-2010 and CARDIOVIT MS-2015 had an issue. Investigation showed that the replacement of the batteries in these cases was overdue (batteries in service for over 5 years). This FSN covers CARDIOVIT MS-2007 since it uses the same battery as other two devices a.m. above. Lacking battery replacement at the recommended interval may lead to battery overheating, generation of smoke and deformation of device housing. To reduce these minor risks the user shall respect the replacement interval for the batteries. According to the User Guide (Ref. to the Pg. 2 for versions) the life time of the battery is 24-month. The battery shall be replaced with a 24-month interval and shall be inspected according to the above-mentioned User Guide. This interval reduces any remote risk from batteries with exceeded lifetime to a minimum.

Advice on action to be taken by Schiller subsidiaries, distributors and customers:

Please note that according to the current User Guides battery shall be replaced with 24-month interval.



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1. Read *User Guide* which is annexed to this field safety notice.
CARDIOVIT MS-2007: 2.511005 Rev. d (English version)
CARDIOVIT MS-2010: 2.510852 Rev. g (English version)
CARDIOVIT MS-2015: 2.510852 Rev. g (English version)
2. Complete acknowledgement form and return to Schiller AG's contact person a.m. below.
Contact your local Schiller technical support team for any technical support.

Transmission of this Field Safety Notice:

Please make sure that all users of the aforementioned devices and other relevant person within your organization will be aware of this new field safety notice.

If your organization passed the devices to third parties, please forward a copy of this information or inform the below mentioned contact person.

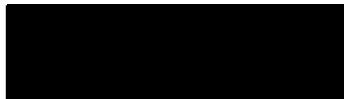
Please maintain awareness on this notice and resulting actions at least until the corrective action has been completed.

The responsible National Competent Authority Swissmedic has been informed about this communication of this field safety notice.

Contact person:

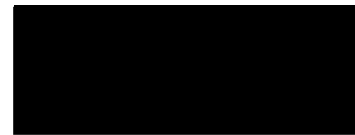
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Quality Assurance Manager

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Dr. Zhenrong Yu
VP, Regulatory Affairs & Quality Assurance

Schiller AG, Switzerland
Date: 22.11.2018



Dr. Johann Jakob Schmid
Senior VP

Schiller AG, Switzerland
Date: 22.11.2018

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