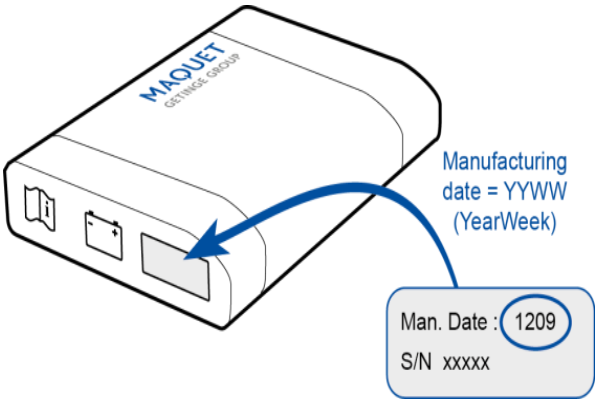
HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Servo-i Ventilator Battery Modules



Part Numbers: 6487180

Manufacturing Dates: 1005- 1243 (February 1, 2010 – October 25, 2012)

Priority 2 – Warning

HPRA Safety Notice: SN2014(39) **Issue Date: 3rd October 2014**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Manufacturer: Maquet (Getinge Group)	V17339

ISSUE
Maquet have identified that when using the SERVO-I on battery power, some battery modules distributed after February 15, 2010 have a shorter battery run time than expected. Shorter battery run time could potentially cause an early power loss of the SERVO-I ventilator system without the normal sequence of alarms and lead to the stoppage of the ventilator.

ACTION OR RECOMMENDATIONS
HPRA advises users to: 1 Ensure that you have read and followed the instructions that were provided in the

manufacturer's field safety notices (FSNs) that were previously circulated by Maquet in March and April 2013.

2 Determine if replacement batteries are required.

3 Complete and return the Response Forms included with the FSNs.

4 Ensure relevant personnel receive a copy of the attached FSNs.

5 Forward the FSNs and this safety notice to any other persons/organisations where these devices have been transferred.

TARGET GROUPS

HSE Hospital Staff	Purchasing Managers
Private Hospital Staff	Supplies Managers
Nursing Home Staff	Risk Managers
Hospital Chief Executive Officers	Clinical Engineering/ Medical Physics

BACKGROUND

Maquet had become aware of a very limited number of cases where during intra-hospital transportation, some battery modules have exhibited a shorter battery run time than expected. Shorter battery run time could potentially cause an early power loss of the SERVO-I ventilator system without the normal sequence of alarms and lead to the stoppage of the ventilator.

In the cases of total power loss, an audible alarm will sound for at least 2 minutes and the SERVO-I will cease operation and enter a "ventilator" state, with open valves.

Batteries with the potentially shorter battery run time can be identified by inspecting the manufacturing date code on the label as outlined in the attached FSNs.

The HPRA is circulating this Safety Notice at this time to ensure that all users of the device are aware of the issue. The HPRA understands from Maquet that despite several communications to customers, they have not received confirmation /acknowledgements from all customers.

MANUFACTURER CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Lars Berken
Director Regulatory Affairs
Maquet Critical Care AB
Rontgenvagen 2
SE-171 54 Solna
Sweden

Telephone: +46 8 730 73 00
Fax: +46 8 730 78 38
E-mail: regulatory.affairs@maquet.com
Website:

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority	**Telephone:**	+353-1-6764971
Kevin O'Malley House	**Fax:**	+353-1-6344033
Earlsfort Centre	**E-mail:**	devicesafety@hpra.ie
Earlsfort Terrace , Dublin 2	**Website:**	www.hpra.ie