

11 July 2011

Hirsham Junaidi
Senior Assistant Director,
Surveillance and Vigilance,
and MDPWG Secretariat

Post Market Unit
Medical Device Bureau
Ministry Of Health Malaysia
Aras 5, Bangunan Plot 3C4,
No.26, Jalan Persiaran Perdana,
Presint 3
62675 Putrajaya

Fisher & Paykel
HEALTHCARE

Fisher & Paykel Healthcare Limited
Stewart Building
15 Maurice Paykel Place, East Tamaki
P O Box 14 348, Panmure
Auckland, New Zealand
Telephone: +64 9 574 0100
Facsimile: +64 9 574 0158
Website: www.fphcare.com

Field Safety Corrective Action
Fisher & Paykel Healthcare SleepStyle™ Series CPAP Power Cord

Dear Hirsham Junaidi,

Thank you very much for contacting Fisher & Paykel Healthcare. We have received your request for additional information with respect to our proposed Field Safety Corrective Action for the power cords provided with Fisher & Paykel Healthcare's SleepStyle™ Series CPAP units. Please find below the answers to your queries.

1. The contact details of appointed Local Authorized Representative(s) available in Malaysia for this products.

Please find the contact details for Fisher & Paykel Healthcare's distributor below:

Veronica Lieu

Daya Cergas (M) Sdn. Bhd.
No. 7, Jalan Setia Tropika 1/2
Taman Setia Tropika
Kempas, 81200 Johor Bahru
Johor, Malaysia

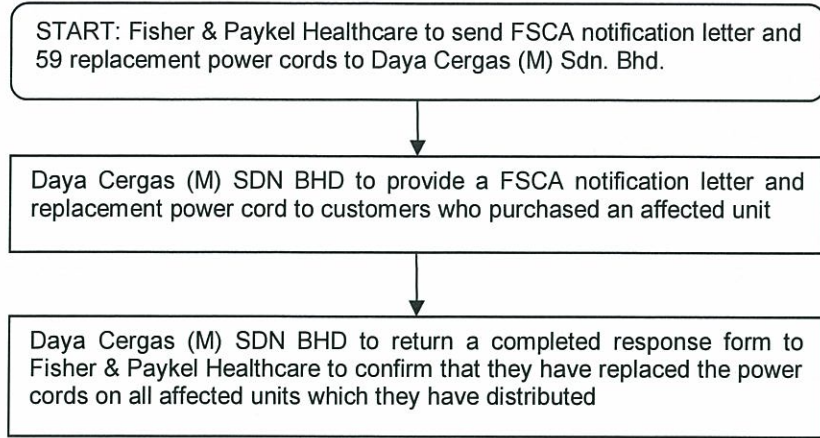
Email: dayacgas@streamyx.com
Telephone: +607-2327455 / 2358455 / 2367455
Fax: +607-2377455

2. Number of affected units (rough estimation) available in Malaysia market.

Fisher & Paykel Healthcare has sold potentially affected 59 units to the Malaysian market between 2006 and the present. It is likely that less than 59 units still remain in the field.

3. The Field Safety Corrective Action plan/strategy designed for this activity and the timeline proposed by the Fisher & Paykel.

This Field Action relates to homecare products which are distributed to end users by distributors. As the contact details for end users are held by the distributors (not by Fisher & Paykel Healthcare), we intend to provide notification letters and replacement product to end users through our Malaysian distributor Daya Cergas (M) Sdn. Bhd. as per the flow chart on the back of this letter.



In an effort to ensure that all affected end users are provided with replacement power cords, Fisher & Paykel Healthcare will follow-up with our distributor three times, or until confirmation that the power cords have been distributed to affected end users is received.

Kind regards,

James Thompson
Regulatory Affairs Manager