COVIDIEN

URGENT MEDICAL DEVICE RECALL for BIS™ Bilateral Sensors

November 8, 2011

Dear Valued Customer,

We are informing you of an urgent voluntary medical device recall regarding the BIS™ Bilateral Sensor, part number 186-0212.

We have determined that a recent modification of the BIS™ Bilateral Sensor reversed the reference electrode and the left eye electrode. This change will result in the inaccurate calculation and presentation of processed EEG information for Bispectral Index™ (BIS), Density Spectral Array (DSA), and Asymmetry (ASYM) values.

Although we have received no reports of patient injury, we have determined that all BIS™ Bilateral Sensors from the lots listed below must be returned. We are requesting your assistance in conducting this activity. Please review your inventory and segregate any product with the affected lot numbers and return affected product according to the directions below.

If you or your company has distributed BIS™ Bilateral Sensors to other persons or facilities, please promptly forward the recipients a copy of this letter. Your customers should complete the verification form and return the completed form with affected units directly to their distributor.

The recall applies to the following 9 lot numbers.

0528111A - 0604111A - 0606111A - 0609111A - 0615111A - 0624111A - 0707111A - 0801111A - 0808111A

Please complete attached Verification Form in his entirety. Please fax or email the completed form to the fax number or email address mentioned on the form. If you do not have any units from the affected lots in your inventory, simply return the verification form indicating you have zero (0) units via fax or email that are mentioned on the form. Your response is vital to our monitoring of the effectiveness of this recall.

Customers that received product directly from COVIDIEN, will be contacted by Customers Services in order to issue credit.
If you purchased product from a Distributor please complete the verification form and contact your Distributor directly. The completed form and all affected units must be returned through the Distributor.

Please report any issues with the BIS™ Bilateral Sensor to **add local contact details** to ensure proper device reporting procedures are followed.

This letter is being sent with the knowledge of the **add name of the local competent authority**

Please pass the FSN on to all those who need to be aware of it within your organization and please maintain awareness over an appropriate defined period.

Please be assured that we are working expeditiously to address this issue in future production and we are aware that this may create supply challenges for your facility.
We sincerely apologize for any inconvenience this may cause and appreciate your prompt attention to this matter.

Sincerely

[redacted]

[redacted]
Vice President, Quality Assurance and Regulatory Affairs
Respiratory and Monitoring Solutions
Covidien

6135 GUNBARREL AVENUE
BOULDER, CO 80301
USA

800-635-5267 [T]

COVIDIEN

[Please insert date the form was sent]

URGENT MEDICAL DEVICE FSCA
BIS Bilateral Sensor

VERIFICATION FORM

Customer Contact Details	Covidien Contact Details
Hospital Name:	**To:** [*please insert name Covidien commercial office*]
Address:	**Address:** [*please insert Covidien address*]
Telephone n°:	**Telephone n°:** [*please insert Covidien telephone number*]
Fax n°:	**Fax n°:** [*please insert Covidien fax number*]
E-mail:	**E-mail:** [*please insert contact e-mail address*]

Please list the quantity of affected product at your facility, if you have no stock, please indicate '0'.

Part number 186-0212		
Lot number	**Qty**	**Please indicate Carton or Each**
0528111A		
0604111A		
0606111A		
0609111A		
0615111A		
0624111A		
0707111A		
0801111A		
0808111A		

Please fax this form to the fax number referenced at the top of this form.

Customer Service will contact you directly to issue credit and to organise return of affected products.

Name:
(please print)

Signature:

Date: