MEDIANA

MEDIANA CO.,LTD
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URGENT DEVICE RECALL

N5600 Plus, N5600Plus/P Multi Parameter Monitors

October 10, 2007

Dear Valued Customer:

Mediana Co., Ltd is conducting a voluntary recall of the N5600 Plus and N5600Plus/P Multi Parameter Monitor distributed by Tyco Healthcare. We have confirmed that under special circumstances, the device does not alarm. This issue only applies to N5600 Plus and N5600/P Plus Multi Parameter Monitors manufactured and shipped between March-20th,2007 and August-31st, 2007.

Our investigation has shown that the recalled devices will experience an alarm failure when the Sat/Second feature is enabled and the SPO2 alarm limits are changed in the general alarm field. If the Sat/Second function is activated and the SpO2 alarm limits are changed in the general alarm field, the device will not generate the SpO2 limit violation alarms even though the measured SpO2 values violate the alarm limits.

Our records indicate that you have received a shipment of N5600 Plus or N5600Plus/P Multi Parameter Monitors from the affected population. Please examine your inventory immediately to determine if you have any of these units on hand. Should any recalled product be found, please remove it from your inventory and place it in quarantine.

To implement this corrective action, a service representative will contact you to upgrade your unit.

Please use the attached list of affected serial numbers to confirm which device(s) within your facility are affected. You can locate the serial number of your monitor at the barcode label attached on the back side of the monitor
If you are a distributor, we request that you notify your customers of this letter.

We regret any inconvenience this matter may cause and appreciate your attention to this notice. This action is

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being conducted with the knowledge of Competent Authorities. If you have any questions or need additional assistance with locating the serial number, please call +82 7070929945

Sincerely,

[redacted] / *QA Manager of Mediana Co., Ltd*

COVIDIEN

URGENT DEVICE RECALL VERIFICATION FORM

N5600PLUS Multiparameter Patient Monitor and N5600PLUS/P Multiparameter Patient Monitor with Printer

Date:	**Page(s) – including this sheet:**
From (Contact:)	**Phone number:**
Facility Name:	**Address:** **Country:**

Monitor Serial Number	Date of Software Upgrade

Name: (Please print):

Signature & Date:

Covidien requires that this form be completed and faxed to

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Comments: