

医療機器回収の概要

(クラス II)

1. 一般名及び販売名

一般の名称： 重要パラメータ付き多項目モニタ  
販売名： 生体情報モニタ IntelliVue

2. 対象ロット、数量及び出荷時期

対象製造番号：

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DE84309998 (\*\*), DE84309999 (\*\*)

対象数量：1669 台(\*\*)

出荷時期：平成 20 年 11 月から平成 24 年 1 月 (\*)

### 3. 製造販売業者等名称

名称 : 株式会社フィリップスエレクトロニクスジャパン  
所在地 : 東京都港区港南 2-13-37 フィリップスビル  
許可の種類 : 第一種医療機器製造販売業  
許可番号 : 13B1X00221  
輸入先製造業者 : フィリップス メディツィン システム ボブリンゲン社  
(ドイツ連邦共和国)

### 4. 回収理由

海外製造元から、当該製品の特定のソフトウェアリビジョンにおいて、ある条件下で、当該製品にてアラームが発生した際、その接続先であるセントラルステーションでアラーム音またはアラーム情報の画面表示が出力されない可能性があるため、当該製品のソフトウェアアップデートを行うとの連絡を受けました。そのため、国内において、自主回収としてソフトウェアのアップデートを行うことと致しました。

### 5. 危惧される具体的な健康被害

本事象が発生した場合、セントラルステーションでアラームが出力されないためセントラルステーションで患者をモニタリングしていた場合、患者への処置の遅れを引き起こす可能性があります。しかしながら、ベッドサイドではアラーム音や、アラーム表示等は正常に出力されるため、医療従事者が患者のアラーム情報を認識することが出来ます。そのため重篤な健康被害発生の可能性は極めて低いと考えます。現在まで、本事象発生に起因すると思われる健康被害発生の報告は受けておりません。

### 6. 回収開始年月日

平成 24 年 2 月 20 日

### 7. 効能・効果又は用途等

本品は、組み込み機能キット、モジュール、他の装置を利用していくつかのモニタリングパラメータを収集し、ベッドや患者別に表示するユニットをいう。ベッドサイドユニットは、セントラルモニタと接続することができるが、単独でも動作可能である。モニタリングパラメータには心電図、血圧、体温、心拍出量、呼吸ガス等があり、加えて脳波測定・解析機能を有し、かつ重要パラメータである不整脈検出・無呼吸検出を行う。

### 8. その他

納入いたしました施設はすべて弊社が把握しておりますので、連絡の上、回収を実施します。

### 9. 担当者及び連絡先

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