

医療機器改修の概要(クラス II)1. 一般名及び販売名

(1) 一般の名称：半自動除細動器

販売名：ハートスタート FR3 Pro

(2) 一般の名称：非医療従事者向け自動除細動器

販売名：ハートスタート FR3

2. 対象ロット、数量及び出荷時期

(1) ハートスタート FR3 Pro

製造番号：

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C13L-00140, C13L-00141, C13L-00201, C13L-00214, C13L-00215, C13L-00216, C13L-00217, C13L-00218,  
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対象台数：1229 台

出荷時期：平成 23 年 9 月から平成 26 年 2 月

(2) ハートスタート FR3

製造番号：

C11F-00013, C11F-00014, C11F-00015, C11F-00088, C11F-00089, C11F-00090, C11F-00091, C11F-00092,  
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C11J-00249, C11J-00261, C11K-00001, C11K-00002, C11K-00003, C11K-00004, C11K-00005, C11K-00006,  
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C13G-00668, C13G-00568, C13G-00572, C13G-00592

対象台数：364 台

出荷時期：平成 23 年 7 月から平成 26 年 1 月

### 3. 製造販売業者等名称

製造販売業者の名称 : 株式会社フィリップスエレクトロニクスジャパン  
製造販売業者の所在地 : 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  
輸入先製造業者名 : フィリップスメディカルシステムズ  
(アメリカ合衆国)

### 4. 改修理由

海外製造元の製品解析の結果、対象機器 (Version 2.0) のバッテリー交換の際に、通常充電されたバッテリーに交換するところ、誤って残量がほぼないバッテリーに交換するようなことがあった場合にアラーム音を発生しない可能性があるとの情報提供がありました。

海外製造元では、この事象を社内評価中に見つけました。また、市場からの情報では、この事象が発生したとの報告はありません。

弊社としましては、予防措置としてソフトウェアをバージョンアップする自主改修を実施致します。

### 5. 危惧される具体的な健康被害

本事象は、バッテリー残量が十分な状態で使用されている場合には発生しません。

また、バッテリー残量が少なくなった場合にはアラーム音によって、バッテリーの状態を使用者に知らせるため、速やかに充電されたバッテリーに交換する事で正常に使用できます。

このため、重篤な健康被害の発生はありません。なお、これまでに健康被害発生の報告はありません。

### 6. 改修開始年月日

平成 26 年 4 月 14 日

### 7. 効能・効果又は用途等

本品は、別に供給される粘着性の除細動電極 (パッド) を介して電気パルスショックを供給することにより心室細動が発現した心臓の除細動を行うことを目的として使用する。

なお、除細動ショックは、除細動電極 (パッド) を介して得られる心電図 (ECG) を解析して要否を判定し、供給すべき時点を操作者に知らせ、手動操作にて供給される。

### 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、改修を実施致します。

### 9. 担当者及び連絡先

担当者 : 小野 英夫、大谷 龍治  
連絡先 : 株式会社フィリップスエレクトロニクスジャパン  
薬事・品質保証本部  
電話番号 : 0120-802-337  
FAX 番号 : 03-3740-5206