

## 医療機器改修の概要

## (クラス II)

## 1. 一般名及び販売名

一般の名称：手動式除細動器  
販売名：ハートスタート MRx

## 2. 対象ロット、数量及び出荷時期

型式番号：M3535A, M3536A

製造番号：

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対象台数：1405 台

出荷時期：平成 21 年 4 月から平成 26 年 11 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

ハートスタート MRx に対する、通常の使用環境では起こりそうにない事象に対する措置や品質向上措置について、海外製造元の指示に基づいて本措置を自主改修として行うことと致しました。

事象 1 :

海外製造元における社内評価試験の中で、当該機器がバッテリー電源ではなく AC 電源または DC 電源に接続して使用されている場合に規格を超える極めて強い EMC ノイズの干渉を受けた場合、当該機器が予期しない動作をする可能性のあることがわかりました。

事象 2 :

海外製造元における社内評価試験の中で、当該機器に外部パドルを接続して、取扱説明書には記載がない通常の取扱い操作では考えられない特異な操作が行われた場合に、当該機器が予期しない動作をする可能性のあることがわかりました。

事象 3 :

海外製造元における社内評価試験の中で、サービスマン等が点検、修理等のメンテナンス作業で使用する当該機器のサービスモード機能において、特定の操作と特殊な条件が重なった場合に、メンテナンス作業を終了した後、通常使用する動作モードで動作させた場合に、当該機器が予期しない動作をする可能性のあることがわかりました。

5. 危惧される具体的な健康被害

事象 1 が発生した場合、予期しない内部放電やペーシング中断が発生して処置が遅れる原因となる、または予期しないタイミングで除細動ショックが行われる可能性があります。規格を越えない EMC ノイズ環境下では発生することはありません。事象 2 は、予期しないタイミングで除細動ショックが行われる可能性があります。取扱説明書に記載されている手順に従って操作される限り発生することはありません。事象 3 が発生した場合、予期しないタイミングで 1 回再起動する可能性があります。サービスモード機能はパスワードロックにより医療関係者は操作できないため当該事象が発生することはありません。当該機器使用中は、医師、救急救命士により常に患者は監視されているため重篤な健康被害につながる可能性はないと考えます。現在まで、国内において、上記事象の発生及びそれに起因すると思われる健康被害発生報告は受けておりません。

6. 改修開始年月日

平成 27 年 10 月 27 日

7. 効能・効果又は用途等

本品は、体外又は体内の電極を介して電気パルスショックを供給することによって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。

本品には、心電図 (ECG) モニタが備わっており、心電図の監視と除細動放電の両方に機能する粘着性の除細動電極 (パッド) を介して患者に装着し、電気パルスショックを供給すべき時点を操作者に知らせる半自動 (AED) モードと、心電図の解析と電気パルスショックを操作者が手動で行う手動モードがある。

8. その他

納入いたしました医療機関、消防機関等は、すべて把握しておりますので連絡の上改修を実施いたします。

9. 担当者及び連絡先

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