

医療機器回収の概要(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 MRxE

(2) 一般の名称：手動式除細動器（半自動除細動器）
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

(1) ハートスタート MRxE

型式番号：M3536J

製造番号：

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対象台数 : 957 台

出荷時期 : 平成 18 年 3 月 20 日から平成 21 年 3 月 24 日

(2) ハートスタート MRx

型式番号 : M3535A, M3536A

製造番号 :

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US00565756, US00565757, US00565773, US00565777, US00565778

対象台数：1221 台

出荷時期：平成 21 年 4 月 28 日から平成 25 年 3 月 7 日

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. 回収理由

海外にて当該機器の使用中に除細動ショックに失敗したとの事例が海外製造元へ報告されました。
海外製造元で調査したところ、極めて稀ではありますが機器の電子基板の障害の発生により、除細動ショック時にパッド ECG 波形が表示できなくなり、エラーメッセージを表示して除細動ショックを失敗するおそれがあることが判明しました。そのため海外製造元より、同障害に対応するため電子基板上のソフトウェアの修正を行うとの連絡を受けました。弊社においても自主回収としてソフトウェアの修正を行うことといたしました。

5. 危惧される具体的な健康被害

当該機器の使用中に本障害が発生した場合、除細動ショックに失敗する可能性があります。
しかしながら、本装置は医療従事者向けのため、使用中は、医師、救急救命士により常に装置および患者は監視されており、異常が発生した場合においても直ちに適切な処置を取ることが出来ますので重篤な健康被害が発生する可能性はないと考えております。
現在まで、国内において本件に起因すると思われる事象および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 25 年 4 月 19 日（情報提供の開始）

7. 効能・効果又は用途等

(1)ハートスタート MRxE

本装置は、救急救命の必要な現場で使用するものであり、心臓の状態が心肺蘇生法を必要とする患者（反応がなく、自発呼吸がなく、脈が触知できない患者）に対して除細動を行うものである。また、本装置は、心電図、SpO₂ のモニタリングとしても使用が可能である。

(2)ハートスタート MRx

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

当該対象製品を納入した医療機関、消防施設は、すべて把握しておりますので、連絡の上、ソフトウェアの修正作業を実施いたします。

9. 担当者及び連絡先

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