

医療機器改修の概要(クラス II)1. 一般名及び販売名

(1) 一般的名称：半自動除細動器

販売名：ハートスタート MRxE

(2) 一般的名称：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

(1) ハートスタート MRxE

型式番号：M3536J

製造番号：

US00209838, US00209839, US00209840, US00209841, US00209842, US00209843, US00209844, US00209845,
US00209846, US00209847, US00209848, US00209849, US00209850, US00209851, US00209853, US00209854,
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US00332670, US00332671, US00332675

対象台数：915 台

出荷時期：平成 18 年 3 月から平成 21 年 3 月

(2) ハートスタート MRx

型式番号：M3535A, M3536A

製造番号：

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US00570133, US00570134, US00571087, US00571097, US00571111, US00571214, US00571218, US00571436,
US00571885

対象台数：713台

出荷時期：平成21年4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

海外製造元からの情報によると、当該機器を院内搬送環境、ならびにプレホスピタル（救急搬送EMS）環境で使用した場合、パッド/パドル除細動ケーブルと機器の除細動ポート間の機械的/電気的接続部に想定以上の負荷がかかることにより、接続部の摩耗を加速させるおそれがあるとのことです。そのため、海外製造元では、当該部分の点検を行うと共に、その負荷や摩耗をより軽減のために製品に付属しているケーブル等固定具の取付を行うとのことです。

弊社としましては、予防措置として同作業を行う自主回収を実施致します。

5. 危惧される具体的な健康被害

当該機器の使用中に本事象に至った場合、除細動ショックの機会を失う、或いは遅延するおそれがあります。しかしながら、通常通り取扱説明書の記載手順に従いケーブル接続部の点検をすることで摩耗状態を事前に確認する事ができます。

また、当該機器使用中は、医師、救急救命士により、常に機器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でき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への報告は受けておりません。

6. 改修開始年月日

平成26年7月22日

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

当該対象機器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、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

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