

お客様各位

株式会社フィリップスエレクトロニクスジャパン

手動式除細動器 ハートスタート XL に関する重要なお知らせ

拝啓

時下、ますますご清祥のこととお慶び申し上げます。平素は格別のご高配を賜り、厚くお礼申し上げます。

このたび、弊社より販売いたしました手動式除細動器 ハートスタートXLのエネルギー選択スイッチの不具合により電源が入らない事象が海外(主に、タイ等東南アジアの熱帯地方でのみ発生。日本、北米および欧州では本事例の発生報告はありません)において報告されました。製造元にて調査した結果、特定の時期に製造されたエネルギー選択スイッチにおいて、管理された通常の状態(室温)下ではない高温多湿状態におかれた場合に、エネルギー選択スイッチ内部部品の経年劣化が助長されるおそれがあることが判明いたしました。

現在まで国内において本事象の発生及び健康被害の報告は受けておりません。また、この不具合の発生により患者様に対して機器を使用した際に処置ができなかったという報告はありません。しかしながら長期の使用において同様の事象が発生する可能性を否定できないため、同時期に製造されたエネルギー選択スイッチを無償で交換する旨、製造元より連絡を受けました。今後本事象発生の可能性は極めて低いものと判断しておりますが、長期信頼性の確保の観点から、国内においても下記のとおり対象製品におけるエネルギー選択スイッチの部品交換を実施致します。

お客様にはご心配、ならびにご迷惑をお掛けしますことを深くお詫び申し上げます。弊社といたしましては、全力をあげて対処し製品の品質および安全の確保につとめていく所存でございますので、ご理解賜りますよう宜しくお願い申し上げます。

敬具

- 記 -

【製品名】 手動式除細動器

【販売名】 ハートスタート XL 【型式】 M4735A

【お客様へのお願い】

弊社または弊社販売店の担当者が訪問し製品の部品交換を致します。交換時期等については別途ご連絡いたします。

尚、それまでの間、可能であれば対象製品の使用を控えていただくか、日常点検およびシフト/システム・チェックを確実に行っていただき、バックアップ体制についてもご配慮くださいますようお願い申し上げます。

この件に関しまして、ご不明な点がございましたら下記 AED コールセンターまでご連絡ください。

株式会社フィリップスエレクトロニクスジャパン
AED コールセンター 0120-802-337
受付時間:9:00~18:00(平日)

手動式除細動器 ハートスタート XL

自主回収対象製造番号リスト (1284 台)

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