2019年10月11日

メドトロニック社製ペースメーカをご使用の患者様

日本メドトロニック株式会社
CRHF事業部

植込み型心臓ペースメーカ「メドトロニックAdapta DR」「メドトロニックAdapta VDD」「メドトロニックVersa DR」「メドトロニック Sensia DR」の自主改修に関して

過日、患者様がご使用中の弊社製ペースメーカ（デュアルチャンバ型）「メドトロニック Adapta DR(アダプタ ディーアール)」「メドトロニック Adapta VDD（アダプタ ブイディーディー）」「メドトロニック Versa DR（バーサ ディーアール）」「メドトロニック Sensia DR（センシア ディーアール)」において特定の条件下で問題が発生する可能性があることが判明したことをお伝えいたしました。

この度、本不具合を解消するため、プログラマを介してご使用中のペースメーカの更新を行います。 当該製品をご使用されている患者様は、かかりつけ医療機関にお問い合わせ頂き、対応方法等の詳細について、医療機関からの指示に従ってご対応いただきますよう、お願い申し上げます。
今後も、患者様からの本件に関するご質問にお答えするとともに、先生方に対し適宜必要な情報を提供していく所存です。

この度は、患者様ならびに患者様のご家族の皆様にご心配とご迷惑をおかけいたしますこと、深くお詫び申し上げます。

【対象製品】

植込み型心臓ペースメーカ（デュアルチャンバ型）

製品名 ：

(1)メドトロニック Adapta DR

(2)メドトロニック Adapta VDD

(3)メドトロニック Versa DR

(4)メドトロニック Sensia DR

製品名：メドトロニック Adapta DR

製造番号：

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製品名：メドトロニック Adapta VDD
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製品名：メドトロニック Versa DR
製造番号：
NWH015000G, NWH015017G, NWH015046G, NWH015073G, NWH015034G,
NWH015016G, NWH015024G, NWH015022G, NWH015038G, NWH015032G,
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NWH015023G, NWH015001G, NWH015027G, NWH015167G, NWH015033G,
NWH015003G, NWH015042G, NWH013967G, NWH015029G, NWH015021G,
NWH015018G, NWH015020G, NWH015026G, NWH015028G, NWH015037G

製品名：メドトロニック Sensia DR
製造番号： 該当なし

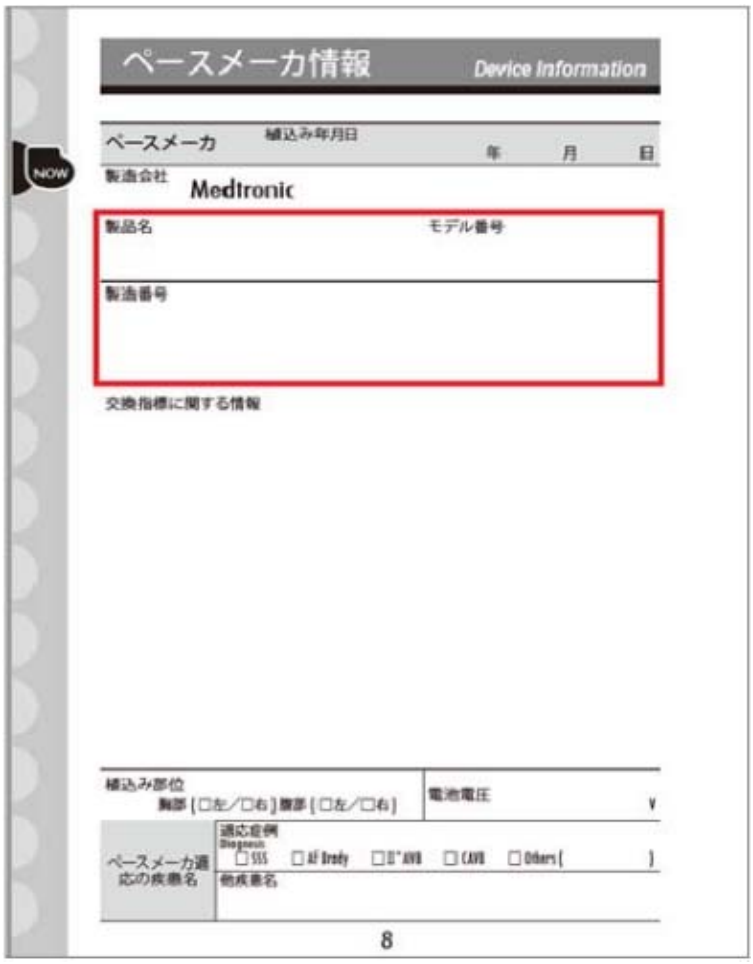
出荷数量：1,158個

2019年10月10日作成

【自主改修対象の製造番号確認方法】

ご使用の製品名、および製造番号はお手持ちのペースメーカ手帳『ペースメーカ情報』からご確認いただけます。

ペースメーカ手帳『ペースメーカ情報』イメージ



製造番号は次のように示されます。

A B C 1 2 3 4 5 6 D

アルファベット　　数字　　アルファベット

【本件に関するお問い合わせ】

本件に関する患者様のお問い合わせ窓口

本件専用のフリーダイヤル 電話番号：0120-911-381

受付時間：平日 9 時-17 時