

医療機器改修の概要  
(クラス II)

## 1. 一般の名称及び販売名

一般の名称：汎用人工呼吸器

販売名：サーボベンチレータ SERVO-air

## 2. 対象ロット、数量及び出荷時期

製造番号：

10170, 10178, 10184, 10188, 10190, 10191, 10192, 10193, 10194, 10195, 10196, 10197, 10198, 10199,  
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24063, 24064, 24065, 24071, 24072, 24073, 24074, 24075, 24076, 24077, 24079, 24080

出荷数量 : 3106 台

出荷時期 : 平成 28 年 4 月 22 日 ~ 令和 4 年 8 月 1 日

### 3. 製造販売業者等名称

製造販売業者の名称 : フクダ電子株式会社  
製造販売業者の所在地 : 東京都文京区本郷三丁目 3 9 番 4 号  
許可の種類 : 第一種医療機器製造販売業  
許可番号 : 13B1X00003

### 4. 改修理由

(1)

輸入先製造業者よりごく稀に呼吸システムのソフトウェアの誤動作によりテクニカルアラーム（アラーム音とメッセージの表示）が発生し換気を停止する可能性があるとの報告を受けました。自主改修として改良したソフトウェアへのアップデートを実施します。

(2)

最新の垂直荷重規格（IEC 60601-1 § 9.4.2.3 b）にユーザーがホイールベースを踏むことにより機器が転倒しないよう記載されています。最新規格適合のためホイールベースを踏まないようにホイールベース部（4 か所）に注意ラベルを貼付します。

### 5. 危惧される具体的な健康被害

ソフトウェアの誤動作が発生した場合、安全弁と呼気弁を開放しアラームが発生するため直ぐに気付くことが出来ます。また、ホイールベースを踏み機器が転倒した場合もその場で気付くことが出来ます。本機は医療従事者の監視下で使用されることから適切に対処する事が出来、重篤な健康被害に至る可能性はないと考えております。尚、国内において健康被害の報告は受けておりません。

6. 改修開始年月日  
令和4年8月31日

7. 効能・効果又は用途等  
本装置は、酸素と空気の混合ガスを機械的調節のもとで、口腔または鼻孔を通じて肺に導入し人工的に呼吸を行わせる人工呼吸器です。

8. その他  
本件に係わる装置の納入先は全て把握しており、納入先に情報を提供するとともに改修を実施致します。

9. 担当者及び連絡先  
担当者 : 田北 徳生、石井 義弘  
連絡先 : フクダ電子株式会社  
東京都文京区本郷二丁目35番8号  
電話番号 : 03(5684)1694  
FAX 番号 : 03(5684)1398